UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL	REPORT	PURSUANT TO	SECTION 13	OR 15(d) O	F THE SECURITIE	S EXCHANGE	ACT	OF 1	1934
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For the fiscal year ended <u>December 31, 2015</u>	
OR	
[] TRANSITION REPORT PURSUANT TO SECTION 13 OR	15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to	
Commission file no	umber <u>01-21617</u>
ProPhase I	ahe Inc
(Exact name of registrant a	,
Delaware	23-2577138
(State or other jurisdiction	(I.R.S. Employer
of incorporation or organization)	Identification No.)
621 N. Shady Retreat Road, Doylestown, Pennsylvania	18901
(Address of principal executive offices)	(Zip Code)
Registrant's telephone number, including area code (215) 345-09	<u>19</u>
Securities registered pursuant to Section 12(b) of the Act:	
Title of each class	Name of each exchange on which registered
The of each class	Traine of each extendings on which registered
Common Stock, \$0.0005 par value per share	NASDAQ Global Market
Common Share Purchase Rights	NASDAQ Global Market
Indicate by check mark if the registrant is a well-known seasoned issuer, a Indicate by check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark if the registrant is not required to file reports pursuant to the check mark in the check ma	nant to Section 13 or Section 15(d) of the Act. Yes [] No [X]
Indicate by check mark whether the registrant (1) has filed all reports req of 1934 during the preceding 12 months (or for such shorter period that the to such filing requirements for the past 90 days. Yes [X] No []	
Indicate by check mark whether the registrant has submitted electronical File required to be submitted and posted pursuant to Rule 405 of Regulat such shorter period that the registrant was required to submit and post such	ion S-T (§229.405 of this chapter) during the preceding 12 months (or
Indicate by check mark if disclosure of delinquent filers pursuant to Ite herein, and will not be contained, to the best of registrant's knowledge, in Part III of this Form 10-K or any amendment to this Form 10-K. [X]	
Indicate by check mark whether the registrant is a large accelerated file company. See definition of "large accelerated filer", "accelerated filer" (Check one):	
Large accelerated filer [] Accelerated filer [] N	fon-accelerated filer [] Smaller reporting company [X]
Indicate by check mark whether the registrant is a shell company (as defin	ed in Rule 12b-2 of the Act). Yes [] No [X]
The aggregate market value of the registrant's voting and non-voting combased on the closing price of the common stock on The NASDAQ Global	
Number of shares of each of the registrant's classes of securities outstandi	ng on March 25, 2016
Common stock, \$0.0005 par value per share: Common share purchase rights:	17,080,776
DOCUMENTS INCORPOR	ATED BY REFERENCE

Information set forth in Part III of this report is incorporated by reference to the registrant's proxy statement for the 2016 annual meeting of stockholders.

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K ("Report") contains "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward looking statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. Many of these factors are beyond our ability to predict. Given the risks and uncertainties surrounding forward-looking statements, you should not place undue reliance on these statements. Forward-looking statements typically are identified by use of terms such as "anticipate", "believe", "plan", "expect", "intend", "may", "will", "should", "estimate", "predict", "potential", "continue" and similar words although some forward-looking statements are expressed differently. This Report may contain forward-looking statements attributed to third parties relating to their estimates regarding the growth of our markets. You are cautioned that such forward looking statements are not guarantees of future performance and that all forward-looking statements address matters that involve risk and uncertainties, and there are many important risks, uncertainties and other factors that could cause our actual results, levels of activity, performance, achievements and prospects, as well as those of the markets we serve, to differ materially from the forward-looking statements contained in this Report.

Such risks and uncertainties include, but are not limited to:

- The ability of our management to successfully implement our business plan and strategy;
- Our ability to fund our operations including the cost and availability of capital and credit;
- Our ability to compete effectively, including our ability to maintain and increase our markets and/or market share in the markets in which we do business;
- Our dependence on sales from our principal product, Cold-EEZE[®], and our ability to successfully develop and commercialize our new products within the cough-cold category or other categories such as dietary supplements;
- Changes in our retail and distribution customers strategic business plans including, but not limited to, (i) expansions, mergers, and/or consolidations, (ii) retail shelf space allocations for products within each outlet and in particular the cough/cold category in which we compete, (iii) changes in their private label assortment and (iv) product selections, distribution allocation, merchandising programs and retail pricing of our products as well as competitive products;
- The general financial and economic uncertainty, fluctuations in consumer confidence and the strength of the United States economy, and their impacts on our business including demand for our products;
- Our ability to protect our proprietary rights;
- Our continued ability to comply with regulations relating to our current products and any new products we develop, including our ability to effectively respond to changes in laws and regulations or the interpretation thereof including changing market rules and evolving federal, state and regional laws and regulations;
- Potential disruptions in our ability to manufacture our products or our access to raw materials;
- Seasonal fluctuations in demand for our products;
- Our ability to attract, retain and motivate our key employees;
- Our ability to pay our debts and meet our liquidity needs; and
- Other risks identified in this Report.

You should also consider carefully the statements under other sections of this Report, including the Risk Factors included in Item 1A, which address additional risks that could cause our actual results to differ from those set forth in any forward-looking statements. Our forward-looking statements speak only as the date of this Report. We undertake no obligation to publicly update or review any forward-looking statements, whether as a result of new information, future developments or otherwise.

Where You Can Find Other Information

ProPhase Labs, Inc. ("we", "us" or the "Company") files periodic and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). We make available on our website (www.ProPhaseLabs.com) free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to or exhibits included in those reports as soon as reasonably practical after we electronically file such materials with or furnish them to the SEC. Information appearing on our website is not part of this Annual Report on Form 10-K. You can also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington D.C. 20549-1004. You may request copies of these documents, upon payment of a duplication fee, by writing the SEC at its principal office at 100 F Street, NE Room 1580, Washington, D.C. 20549-1004. In addition, the SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements regarding issuers that file electronically with the SEC, including the Company.

Item 1. Business

General Development of Business

We are a manufacturer, marketer and distributor of a diversified range of homeopathic and health care products that are offered to the general public. We are also engaged in the research and development of potential over-the-counter ("OTC") drug, natural base health products along with supplements, personal care and cosmeceutical products.

Our primary business is the manufacture, distribution, marketing and sale of OTC health care and cold remedy products to consumers through national chain, regional, specialty and local retail stores. Our flagship brand is Cold-EEZE® and our principal product is Cold-EEZE® cold remedy zinc gluconate lozenges, proven in clinical studies to reduce the duration and severity of symptoms of the common cold. In addition to Cold-EEZE® cold remedy lozenges, we market and distribute non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE® cold remedy QuickMelts® and (ii) Cold-EEZE® cold remedy Oral Spray. In Fiscal 2013, we expanded our Cold-EEZE® cold remedy QuickMelts® product line and began shipments to retailers in July 2013 Cold-EEZE® Plus Immune Support + Energy QuickMelts®. In Fiscal 2014 we began shipments in June 2014 of Cold-EEZE® Plus Natural Multi-Symptom QuickMelts®. Each of these new Cold-EEZE® QuickMelts® products are based on our proprietary zinc gluconate formulation in combination with certain natural (i) immune system support, (ii) energy, (iii) sleep and relaxation, and/or (iv) cold and flu symptom relieving active ingredients. In Fiscal 2015, we introduced three new Cold-EEZE® product line extensions: (i) a Cold-EEZE® Multi-Symptom Relief for Cold and Flu lozenge, (ii) a Cold-EEZE® Daytime and Nighttime Multi-Symptom Relief in liquid form for each of adults and children, and (iii) Cold-EEZE® Natural Allergy Relief caplets for indoor and outdoor allergies. Shipments for these three new Cold-EEZE® product line extensions began in the third quarter of Fiscal 2015.

Cold-EEZE® is an established product in the health care and cough-cold market. For Fiscal 2015, 2014 and 2013, our revenues have come principally from our OTC health care and cold remedy products. For Fiscal 2015, 2014 and 2013, our net sales for each period were related to markets in the United States.

We use a December 31 year-end for financial reporting purposes. References herein to the fiscal year ended December 31, 2015 shall be the term "Fiscal 2015" and references to other "Fiscal" years shall mean the year, which ended on December 31 of the year indicated.

We were initially organized as a corporation in Nevada in July 1989. Effective June 18, 2015, we changed our state of incorporation from the State of Nevada to the State of Delaware. Our principal executive offices are located at 621 N. Shady Retreat Road, Doylestown, Pennsylvania 18901 and our telephone number is 215-345-0919. The terms, "we", "us" and the "Company" refer to the Company together with its consolidated subsidiaries unless the context otherwise requires.

Description of Business Operations

Cold-EEZE® is our most popular OTC health care and cold remedy product. Cold-EEZE cold remedy lozenges, QuickMelts® and Oral Spray product benefits are derived from our proprietary zinc gluconate formulation. Cold-EEZE® cold remedy lozenges effectiveness has been substantiated in two double-blind clinical studies proving that Cold-EEZE® cold remedy lozenges reduce the duration of the common cold by 42%. We acquired worldwide manufacturing and distribution rights to our lozenge formulation in 1992 and commenced national marketing in 1996. In addition to our lozenge product, the Cold-EEZE® Cold Remedy proprietary zinc gluconate formulation is available in two additional cold remedy delivery forms, (i) a fast dissolving QuickMelt and (ii) an Oral Spray. We also offer our product line extensions (i) Cold-EEZE® Daytime and Nighttime Multi-Symptom Relief in liquid for each of adults and children (ii) Cold-EEZE® Natural Allergy Relief caplets for indoor and outdoor allergies. The demand for our OTC cold remedy products is seasonal and the first and fourth quarters of each year generally have the largest sales volume.

Our business operations are concentrated on the development, manufacturing, marketing and distribution of our proprietary Cold-EEZE® cold remedy lozenge products and on the development of various product extensions. Our product line of OTC health care and cold remedy products are reviewed regularly to identify new consumer opportunities and/or trends in flavor, convenience, packaging and delivery systems or forms to help improve market share for our products.

Although we continue to expand our Cold-EEZE® product offerings, some retailers are limiting and/or reallocating shelf and promotional space away from the cough-cold category to other product categories. With cough-cold shelf and promotional space at a premium, opportunities in the future to introduce new Cold-EEZE® products in the cough-cold category may be limited. Therefore, to continue to grow our Company, we are in the process of implementing a series of new product development and pre-commercialization initiatives in the dietary supplement category.

Initial dietary supplement product development activities were completed in the fourth quarter of Fiscal 2015 under the brand name of TK SupplementsTM. The inaugural TK SupplementsTM product line is comprised of three men's health products: (i) Legendz XLTM for sexual health, (ii) Triple Edge XLTM, a daily energy booster plus testosterone support, and (iii) Super ProstaFlow *Plus*TM for prostate and urinary health. The first of these three TK SupplementsTM products, Legendz XLTM, is scheduled for launch in the first half of Fiscal 2016. Initially, it will be introduced to consumers through direct to consumer marketing including DRTV. If this initial launch is successful, Legendz XL (as well as the other products under development) may ultimately be distributed to retailers, leveraging our Cold-EEZE distribution platform and infrastructure. While management anticipates the growth potential in this category may be better, the risks associated with introducing new products that do not leverage the Cold-EEZE® brand name may be higher. Therefore, no assurance can be made that our new product efforts will be successful.

Additionally, we are active in exploring new product technologies, applications, product line extensions and other new product opportunities consistent with our Company and brand image, and our standard of proven consumer benefit and efficacy.

Manufacturing Facility

Our wholly owned subsidiary, Pharmaloz Manufacturing, Inc. ("PMI"), produces our Cold-EEZE® cold remedy lozenges and other lozenge products in addition to performing operational tasks such as warehousing, customer order processing and shipping. Our PMI facility is located in Lebanon, Pennsylvania. Additionally, our PMI facility is a United States Food and Drug Administration ("FDA") registered facility that engages in contract manufacturing and distribution activities. PMI also produces and sells therapeutic lozenges to unaffiliated third party retail, wholesale and distribution outlets.

Products

OTC Health Care and Cold-Remedy Products

In May 1992, we entered into an exclusive agreement for worldwide representation, manufacturing and marketing of a zinc gluconate formulation. This zinc gluconate formulation is the foundation of our brand; Cold-EEZE® health care and cold remedy products which are distributed principally in the United States. Cold-EEZE® cold remedy products are an OTC consumer product used to reduce the duration of the common cold. We have substantiated the effectiveness of Cold-EEZE® cold remedy lozenges through a variety of studies. A randomized double-blind placebo-controlled study, conducted at Dartmouth College of Health Science, Hanover, New Hampshire, concluded that the lozenge formulation treatment, initiated within 48 hours of symptom onset, resulted in a significant reduction in the total duration of the common cold.

On May 22, 1992, "Zinc and the Common Cold, a Controlled Clinical Study," was published in England in the *Journal of International Medical Research*, Volume 20, Number 3, Pages 234-246. According to this publication, (a) flavorings used in other zinc lozenge products (citrate, tartrate, separate, orotate, picolinate, mannitol or sorbitol) render the zinc inactive and unavailable to the patient's nasal passages, mouth and throat where cold symptoms have to be treated, (b) this patented formulation delivers approximately 93% of the active zinc to the mucosal surfaces and (c) the patient has the same sequence of symptoms as in the absence of treatment but goes through the phases at an accelerated rate and with reduced symptom severity.

On July 15, 1996, results of a randomized double-blind placebo-controlled study on the common cold, which commenced at the Cleveland Clinic Foundation on October 3, 1994, were published. The study "Zinc Gluconate Lozenges for Treating the Common Cold" was completed and published in *The Annals of Internal Medicine* – Volume 125 Number 2. Using a 13.3 mg lozenge (almost half the strength of the lozenge used in the Dartmouth study), the result still showed a 42% reduction in the duration of common cold symptoms.

In addition to our Cold-EEZE® cold remedy lozenges, we also market and distribute non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE® cold remedy QuickMelts® are fast dissolving tablets that are taken orally and (ii) Cold-EEZE® cold remedy Oral Spray a liquid form of our zinc gluconate formulation that is sprayed in the mouth. The Cold-EEZE® cold remedy QuickMelts® product line is comprised of (i) Cold-EEZE® Daytime/Nighttime QuickMelts® (launched in Fiscal 2012) (ii) Cold-EEZE® Plus Immune Support + Energy QuickMelts® (launched in Fiscal 2013) and (iii) Cold-EEZE® Plus Multi-Symptom QuickMelts® (launched in Fiscal 2014).

We also manufacture, market and distribute organic cough drops and a Vitamin C supplement and perform contract manufacturing services of cough drop, dietary supplements, and other OTC cold remedy products for third parties.

In Fiscal 2015, we introduced (i) a Cold-EEZE® Multi-Symptom Relief for Cold and Flu lozenge, (ii) a Cold-EEZE® Daytime and Nighttime Multi-Symptom Relief in liquid form for each of adults and children, and (iii) Cold-EEZE® Natural Allergy Relief caplets for indoor and outdoor allergies. Shipments for these three new Cold-EEZE® product line extensions began in the third quarter of Fiscal 2015. Our new multi-symptom lozenge contains the same proprietary cold shortening zinc gluconate formulation plus additional active ingredients for temporary relief of flu symptoms, cough, and sore and irritated throat. Our Cold-EEZE® Daytime and Nighttime Multi-Symptom Relief in liquid form provide temporary relief of cold and flu symptoms. Our Cold-EEZE® Natural Allergy Relief caplets provide temporary relief of indoor and outdoor allergy symptoms.

Our business is subject to federal and state health and safety laws and regulations. Our OTC health care and cold remedies are subject to regulations by various federal, state and local agencies, including the FDA. Additionally, Cold-EEZE® homeopathic cold remedy lozenges, QuickMelts®, Oral Spray and Allergy caplets are subject to the Homeopathic Pharmacopoeia of the United States. See "Regulatory Matters" below for more information.

Patents, Trademarks, Royalty and Commission Agreements

Patents and Trademarks

We do not currently own patents for our OTC health care and cold-remedy products. We maintain various trademarks for each of our products including Cold-EEZE[®], QuickMelts[®], Organix Rx Complete[®] and Organix Rx Defense[®], ORXx CompleteTM and ORXx DefenseTM, TK SupplementsTM, Legendz XLTM, TripleEdge XLTM and Super ProstaFlow *Plus*TM.

We currently own various domestic and international patents covering certain product development initiatives principally developed under our Pharma subsidiary operations. To date, we have not realized any meaningful levels of revenues from such patents and we suspended in Fiscal 2009 any further commercialization efforts for various products under such patents.

Joint Venture

On March 22, 2010, we, Phosphagenics Limited ("PSI Parent"), an Australian corporation, Phosphagenics Inc. ("PSI"), a Delaware corporation and subsidiary of PSI Parent, and Phusion LLC ("Phusion"), a Delaware limited liability company, entered into a Limited Liability Company Agreement (the "LLC Agreement") of the Phusion joint venture and additional related agreements for the purpose of developing and commercializing, for worldwide distribution and sale, a wide range of non-prescription remedies using PSI Parent's proprietary patented TPMTM technology ("TPM"). TPM facilitates the delivery and depth of penetration of active molecules in pharmaceutical, nutraceutical, and other products. Pursuant to the LLC Agreement, we and PSI each own a 50% membership interest in the Phusion joint venture.

Our Phusion joint venture has (i) an exclusive, royalty-free, world-wide (subject to certain limitations), paid-up license to exploit OTC drugs (and certain other products) that embody certain PSI Parent's TPM-related patents and related know-how (collectively, the "PSI Technology") and (ii) a non-exclusive, royalty-free, world-wide (subject to certain limitations) paid-up license to exploit certain compounds that embody the PSI Technology for use in a product combining one or more of such compounds with an OTC drug or in a product that is part of a regimen that includes the application of an OTC drug (see Note 10 to Notes to Consolidated Financial Statements).

On October 17, 2014, we initiated a demand for arbitration with the American Arbitration Association, case number 01-14-0001-7373. This demand for arbitration pertains to our Phusion joint venture and the matter is against PSI Parent and PSI (collectively known as the "Phosphagenics Entities") (see Item 3. Legal Proceedings).

TK Supplements TM

On June 30, 2015, we executed a Direct Response Production Agreement ("DRPA") with Pacific Custom Video Productions Inc. ("PCV") to produce a series of direct response television commercials for certain TK SupplementsTM products. The cost of the commercial development was \$300,000 which was paid in Fiscal 2015 and is included as a component of prepaid expenses at December 31, 2015. As TK SupplementsTM products are launched in Fiscal 2016, these costs will be charged to operations as the products are shipped and television commercial air time is purchased and broadcasted. In addition, the Company agreed to pay to PCV a three percent performance incentive in the form of a royalty (aka commission) of net sales collected, as defined in the agreement, of certain TK SupplementsTM products marketed and promoted with PCV. Performance incentive fees have not been incurred in Fiscal 2015 and will not be incurred until the TK SupplementsTM product line is launched which is scheduled to commence in the first half of Fiscal 2016.

Product Distribution and Customers

Currently, our products are distributed through national chain, regional, specialty and local retail stores throughout the United States. Revenues for Fiscal 2015, 2014 and 2013 were \$20.6 million, \$22.1 million and \$25.0 million, respectively. Walgreen Company ("Walgreens") and Wal-Mart Stores Inc ("Wal-Mart") accounted for approximately 15.8% and 11.3%, respectively, for Fiscal 2015. Walgreens, Wal-Mart and CVS Health Corporation ("CVS") accounted for approximately 18.9%, 16.9% and 11.3%, respectively, of our Fiscal 2014 revenues. Walgreens, Wal-Mart and CVS accounted for approximately 20.4%, 14.3% and 11.6%, respectively, of our Fiscal 2013 revenues. The loss of sales to any one or more of these large retail customers could have a material adverse effect on our business operations and financial condition.

In addition, we have entered into multiple broker, distributor and representative agreements with third parties which provide for commission compensation based on sales performance.

Research and Development

We have historically invested significantly in research and development activities. Our research and development costs for Fiscal 2015, 2014 and 2013 were \$1.1 million, \$1.3 million and \$824,000 respectively. Our research and development initiatives have been principally focused on product line development and/or line extensions for OTC health care and cold remedy products under the Cold-EEZE® and TK SupplementsTM brands.

Currently, we fund our research and development costs with cash generated from operations. In addition to funding from operations, we may seek to raise capital through the issuance of securities or to other financing sources to support our research and development activities including new product technologies, applications, licensing, commercialization and other development opportunities, as well as acquisitions of new formulations, ingredients, applications and other products. Any such funding through the issuance of our equity securities would result in the dilution of current stockholder ownership. Should research or commercialization activity progress on certain formulations, resulting expenditures may require substantial financial support and may necessitate the consideration of alternative approaches such as licensing, joint venture or partnership arrangements that meet our long term goals and objectives. Ultimately, should internal working capital be insufficient and external funding methods or other business arrangements become unattainable, it could result in the deferral or loss of future growth and development opportunities.

Regulatory Matters

We are subject to federal and state laws and regulations adopted for the health and safety of users of pharmaceutical and health care products. Our OTC health care and cold remedy products are subject to regulation by various federal, state, and local agencies, including the FDA. In addition, our Cold-EEZE® cold remedy products are subject to the standards established by the Homeopathic Pharmacopoeia of the United States. These regulatory authorities have broad powers, and we may be subject to regulatory and legislative changes that can affect the economics of the industry by requiring changes in operating practices or by influencing the demand for and the costs of manufacturing or distributing its products. Our Cold-EEZE® cold remedy products are considered a homeopathic drug and are exempt from pre-approval requirements and other, but not all, FDA requirements.

Many homeopathic drug and dietary supplement products, including Cold-EEZE® cold remedy and TK SupplementsTM products, are manufactured and distributed under FDA enforcement policies that provide criteria needed to market a homeopathic OTC drug or dietary supplement products without FDA approval. We believe we meet those requirements, which include registration of our manufacturing facility, listing of the product in FDA's product database, and packaging, labeling, and manufacturing homeopathic drugs and dietary supplements in compliance with current good manufacturing practice ("cGMP") regulations. In addition, the FDA is currently not enforcing the requirement for a laboratory determination of identity and strength of each active ingredient prior to release for distribution, although this exemption is pending FDA review and we cannot assure that the exemption will be permanently implemented. We also cannot assure that the FDA will agree with our determination of compliance. If the FDA disagrees, the FDA could, upon inspection, issue a notice of violations, referred to as a form FDA-483, or issue a Warning Letter, or both. If we fail to take timely corrective actions to the satisfaction of FDA, the agency can initiate legal actions, such as seizure and injunction, which could include a recall order or the entry of a consent decree, or both. In addition, we could be subject to monetary penalties and even criminal prosecution for egregious conduct. We believe that we are in compliance with all such laws, regulations, and standards currently in effect including the Food, Drug, and Cosmetics Act as amended from time to time, and the standards established under the Homeopathic Pharmacopoeia of the United States.

Pre-clinical development, clinical trials, product manufacturing, labeling, marketing, distribution and licensing and/or acquisition of potential new products are also generally subject to federal and state regulation in the United States and other countries. Obtaining FDA and any other required regulatory approval for certain OTC products, or seeking the issuance of a final monograph from the FDA for certain OTC products, can require substantial resources and take several years. The length of this process depends on the type, complexity and novelty of the product and the nature of the disease or other indications to be treated. If we cannot obtain regulatory approval of, or final OTC monograph for, a new product(s) in a timely manner or if patents are not granted or are subsequently challenged, it could have a material adverse effect on our business and financial condition.

Competition

We compete with other suppliers of OTC cold remedy and health care products. These suppliers range widely in size. Some of our competitors have significantly greater financial, technical or marketing resources than we do. Management believes that our Cold-EEZE® cold remedy lozenge products, which have been clinically proven in two double-blind studies to reduce the severity of common cold symptoms, offer a significant advantage over many of our competitors in the OTC cold remedy market. We believe that our ability to compete depends on a number of factors, including product quality and price, availability, speed to market, consumer marketing, reliability, credit terms, brand name recognition, delivery time and post-sale service and support.

Employees

At December 31, 2015, we employed 54 full-time employees and no part-time employee, the majority of which were employed at our manufacturing facility in a production function. The remaining employees were involved in an executive, sales, marketing or administrative capacity. None of our employees are covered by a collective bargaining agreement or are members of a union.

Suppliers; Raw Materials

We derive our sales principally from our Cold-EEZE® cold remedy zinc gluconate products which are available in various forms-lozenges, oral spray and QuickMelts® – and various flavors for purchase by consumers at retail stores. We also produce private label lozenge products for sale to certain retail customers. We manufacture our zinc lozenge products at our Lebanon, Pennsylvania facility. The constituent raw materials and packaging used in the manufacture and presentation of these items are procured from various sources with additional suppliers having been identified in the event that alternatives are required. While the absence of a current raw materials or packaging source may cause short term interruption, we expect that identified alternative sources would fill our needs in a short time and any transition period would be mitigated by adequate levels of finished product available for sale. Certain products within our line of products such as Cold-EEZE® cold remedy Oral Spray, Cold-EEZE® cold remedy QuickMelts®, Cold-EEZE® Daytime and Nighttime Multi-Symptom Relief in liquid form and Cold-EEZE® Natural Allergy Relief caplets are manufactured for us by various third party contract manufacturers and while currently purchased from single sources, we have identified additional suppliers in the event that alternatives are required. We anticipate that if alternative supplies become necessary, they would fill our needs in a short time and any transition period would be mitigated by adequate levels of finished product available for sale.

Item 1A. Risk Factors

Any of the following risks could materially affect our business, financial condition, or results of operations. These risks could also cause our actual results to differ materially from those indicated in the forward-looking statements contained herein and elsewhere. The risks described below are not the only risks facing us. Additional risks not currently known to us or those we currently deem to be immaterial may also materially and adversely affect our business, financial condition or results of operations.

Our business is subject to significant competitive pressures

The OTC healthcare product, pharmaceutical, dietary supplement and consumer product industries are highly competitive. Many of our competitors have substantially greater capital resources, technical staffs, facilities, marketing resources, product development, distribution and experience than we do. Our competitors may have certain advantages, including the ability to allocate greater resources for new product development, marketing and other purposes.

We believe that our ability to compete depends on a number of factors, including product quality and price, availability, speed to market, consumer marketing, reliability, credit terms, brand name recognition, delivery time and post-sale service and support, and new and existing product innovation and commercialization. There can be no assurance that we will be able to compete successfully in the future. If we are unable to compete effectively, our earnings may be significantly negatively impacted.

Cough-cold category and product innovation

Our flagship Cold-EEZE® cold remedy brand is an established brand within the cough-cold category. However, some retailers are reallocating shelf space away from the cough-cold category to other product categories. With cough-cold shelf space at a premium, opportunities in the future to introduce new Cold-EEZE® branded products in the cough-cold category may be limited. Therefore, to continue to grow our Company, we are in the process of implementing a series of new product development and pre-commercialization initiatives in the dietary supplement category. While management anticipates the growth potential in this product category may be better, the risks associated with introducing new products that do not leverage the Cold-EEZE® brand name may be significant. Therefore, no assurance can be made that our new product efforts will be successful.

New product development; our long range business plan may not be successful

We face significant technological risks inherent in developing new products. We may be subject to delays and/or ultimately unable to successfully implement our business plan and strategy to develop and commercialize one or more non-prescription remedies and/or dietary supplements. The commercialization and ultimate product market acceptance is subject to, among other influences, consumer purchasing trends, demand for our product, health and wellness trends, regulatory factors, retail acceptance and overall economic and market conditions. As a consequence, we may suspend or abandon some or all of our proposed new products before they become commercially viable. Even if we develop and obtain approval of a new product, if we cannot successfully commercialize it in a timely manner, our business and financial condition may be materially adversely affected.

We have aligned our operations to focus principally in the research, development, manufacture, marketing and sale of OTC health care and cold remedy consumer products, natural based health products and more recently, dietary supplement products. In addition, we may seek to acquire from third parties or enter into other arrangements with respect to new formulations, ingredients, applications and other products developed by third parties who may be seeking our commercialization, marketing and distribution expertise.

There can be no assurance that we will be able to effectuate our business plan successfully or that our revenue will grow. In addition, we may not be successful in acquiring or otherwise entering into any new lines of business, including dietary supplement products, and, if we are successful in doing so, there can be no assurance that such new business will achieve profitability.

We will need to obtain additional capital to support long term product development and commercialization programs

Our ability to achieve and sustain operating profitability depends in large part on our ability to commence, execute and complete new and existing product innovation and commercialization and, if required, clinical programs to obtain regulatory approvals in the United States and elsewhere. We can give no assurance that we will be able to achieve such product innovation and commercialization, to obtain any required approvals or to achieve significant levels of sales.

The amount of capital that may be needed to complete product development initiatives will depend on many factors which may include but are not limited to (i) the cost involved in applying for and obtaining FDA, international regulatory or other technical approvals, (ii) whether we elect to establish partnering arrangements for development, sales, manufacturing and marketing of such products, (iii) the level of future sales of OTC health care, cold remedy or dietary supplement products, and expense levels for marketing efforts, (iv) whether we can establish and maintain strategic arrangements for development, sales, manufacturing and marketing of our products, and (v) whether any or all of the options for our common stock, \$0.0005 par value, ("Common Stock") issued to employees of the Company are exercised and the timing and amount of these exercises.

Should research or commercialization activity progress on certain formulations, resulting expenditures may require substantial financial support. The current sales level of our OTC health care and cold remedy products may not generate all the funds we anticipate will be needed to support future product acquisition or development. Accordingly, in addition to funding from operations, we may in the short and long term seek to raise capital through the issuance of securities or to secure other financing sources to support our research, new product technologies, applications, licensing, commercialization and other development opportunities. If we obtain such funding through the issuance of equity securities, it would result in the dilution of current stockholders' ownership in the Company. Any debt financing, if available, may include financial and other covenants that could restrict use of proceeds of such financing or impose other business and financial restrictions on us. In addition, we may consider alternative approaches such as licensing, joint venture, or partnership arrangements to provide long term capital. There can be no assurances that we will have access to the capital required to fun these aspects of our business on favorable terms or at all.

We may not be able to access our Equity Line of Credit under commercially reasonable terms

On July 30, 2015 we executed a new equity line of credit agreement (such arrangement, the "2015 Equity Line") with Dutchess Opportunity Fund II LP ("Dutchess") whereby, Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,200,000 shares of the Company's Common Stock, over a period of 36 months expiring August 2018.

In Fiscal 2015, we sold an aggregate of 438,480 shares of Common Stock to Dutchess under a previous 2014 equity line of credit with Dutchess in which we derived net proceeds of \$524,000. In addition, we sold an aggregate of 750,000 shares of Common Stock to Dutchess under the 2015 Equity Line in which we derived net proceeds of \$1.0 million. At March 25, 2016, we have 2,450,000 shares of our Common Stock available for sale, at our discretion, under the terms of the 2015 Equity Line and covered pursuant to a registration statement.

Pursuant to the 2015 Equity Line, Dutchess is committed to purchase, subject to certain conditions, the remaining 2,450,000 shares of our Common Stock from time to time through August 2018. Dutchess will not be obligated to purchase shares under the 2015 Equity Line unless certain conditions are met, which include, among others: effectiveness of the registration statement; the continued listing of our stock on either the NASDAQ Global Market (our current listing), NASDAQ Capital Market or OTC Bulletin Board; our compliance with our obligations under the purchase agreement and registration rights agreement entered into with Dutchess; the absence of injunctions or other governmental actions prohibiting the issuance of our Common Stock to Dutchess; the absence of violations of shareholder approval requirements with respect to such issuance of our Common Stock to Dutchess and the accuracy of representations and warranties made to Dutchess. If we are unable to access funds through the 2015 Equity Line, we may be unable to access capital on favorable terms or at all.

To the extent that we do not generate sufficient cash from operations, we may need to access our 2015 Equity Line to finance our growth. Our 2015 Equity Line is limited and may not be sufficient to meet our capital requirements. If we need to seek other sources of capital, uncertainty in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through our 2015 Equity Line on terms that we believe to be reasonable, or at all.

Any draw downs under our 2015 Equity Line with Dutchess may result in dilution to our shareholders

If we sell shares to Dutchess under the 2015 Equity Line, it will have a dilutive effect on the holdings of our current shareholders, and may result in downward pressure on the price of our Common Stock. If we draw down amounts under the 2015 Equity Line, we will issue shares to Dutchess at a discount of 5% from the average price of our Common Stock. If we draw down amounts under the 2015 Equity Line when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

We may be unable to generate sufficient cash flows from operations to meet our debt service payments

On December 11, 2015, we executed two Subscription Agreements (the "Subscription Agreements") with the investors named therein (the "Investors") providing for the purchase of 12% Secured Promissory Notes – Series A ("Notes") in the aggregate principal amount of up to \$3.0 million and warrants to purchase shares of our Common Stock (the "Warrants"). The Warrants grant the Investors the right to purchase 17,000 shares of common stock for every \$500,000 of principal amount of Notes purchased by the Investors.

Notes in the amount of \$1,500,000 and 51,000 Warrants, at an exercise price of \$1.35 per share, were issued by the Company and its wholly-owned subsidiaries Pharmaloz Manufacturing Inc. and Quigley Pharma Inc. (collectively, the "Obligors") and funded on December 11, 2015. The Notes are secured by all of our tangible and intangible assets. The Notes bear interest at the rate of 12% per annum, payable semi-annually and the principal is due and payable on June 15, 2017. The Notes may be pre-paid at any time prior to maturity without penalty.

As of December 31, 2015, we had total secured Notes outstanding of \$1.5 million, excluding \$34,000 in unamortized interest for loan origination costs and the fair value of the Warrants. We may incur additional debt to finance future research and development, and product launch and related marketing activities.

Our ability to generate sufficient cash flows from operations to make scheduled debt service payments depends on a range of economic, competitive and business factors, many of which are outside of our control. Our business may generate insufficient cash flows from operations to meet our debt service and other obligations, and currently anticipated cost savings, capital investment plans, working capital reductions and operating improvements may not be realized on schedule, or at all. To the extent our cash flow from operations is insufficient to fund our debt service obligations, aside from our current liquidity, we would be dependent on outside capital to meet the funding of our debt service obligations and to fund capital expenditures and other obligations.

If we are unable to meet our expenses and debt service obligations, we may need to refinance all or a portion of our indebtedness on or before maturity, sell assets or issue additional equity securities. We may be unable to refinance any of our indebtedness, sell assets or issue equity securities on commercially reasonable terms, or at all, which could cause us to default on our obligations and result in the acceleration of our debt obligations. Our inability to generate sufficient cash flows to satisfy our outstanding debt obligations, or to refinance our obligations on commercially reasonable terms, would have a material adverse effect on our business, financial condition and results of operations.

<u>Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations and cash flows</u>

In recent years, there has been substantial volatility in financial markets due at least in part to the global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to financing is uncertain. Moreover, customer spending habits may be adversely affected by the current economic environment and prevailing high under employment rates in the United States. These conditions could have an adverse effect on our industry and business, including our access to funding sources, demand for our products and our customers' ability to continue to purchase our products, which could have a material adverse effect on our financial condition, results of operations and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to issue equity or to incur indebtedness to finance our growth. Turmoil and volatility in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowings, under either existing or newly created instruments in the public or private markets on terms that we believe to be reasonable, or at all.

Commodity price increases will increase our operating costs and may negatively affect financial results

Commodity prices impact our business directly through the cost of raw materials used to make our products (such as corn syrup, sucrose and other commodities and ingredients) and the amount we pay to purchase packaging for our products (such as paper, board and plastic). Commodities such as these are susceptible to price volatility caused by conditions outside of our control, including fluctuations in commodities markets, currency fluctuations, availability of supply, weather, consumer demand and changes in governmental agricultural programs. Increases in the price of our commodities and other raw materials would negatively impact our gross margins and/or our sales volume if we were unable to offset such increases through increases in our selling price, changes in product mix or cost reduction/productivity enhancement efforts.

The sales of our primary product fluctuates by season and from Cold Season to Cold Season

Our sales are derived principally from our OTC health care and cold remedy products. A significant portion of our business is highly seasonal, which causes major variations in operating results from quarter to quarter. The first and fourth quarters generally represent the largest sales volume for our OTC health care and cold remedy products. In addition, our sales are influenced by and subject to fluctuations in the timing of purchase and the ultimate level of demand for our products which are a function of the timing, length and severity of each cold season. Generally, a Cold Season is defined as the period of September to March when the incidence of the common cold rises as a consequence of the change in weather and other factors.

There can be no assurance that we will be able to manage our working capital needs and inventory to meet the fluctuating demand for these products. Failure to accurately predict and respond to consumer demand may result in the production of excess inventory which may be expensive to store or which we may be required to dispose if such excess inventory remains unsold. Conversely, if products achieve greater success than anticipated for any given quarter, this may result in insufficient inventory to meet customer demand. If we do not manage our working capital needs and inventory, our business and financial condition may be materially adversely affected.

Our performance may fluctuate when our retail customers are affected simultaneously by the same economic, regulatory or health and wellness factors

Our revenues are significantly concentrated in our OTC health care and cold remedy products. Our retail customers are subject to fluctuations of business based upon consumer purchasing trends, demand for cold remedy products and overall economic and market conditions. Consequently, many retailers will likely be influenced at the same time by similar economic conditions, regulatory factors or health and wellness trends, which can affect the level of demand for our products. It is reasonable to expect that, if one retailer reduces or delays its purchasing in response to a general economic, regulatory or health and wellness factor, other retailers may also decide to reduce or delay their purchasing at approximately the same time. Accordingly, our sales are subject to fluctuations as a result of such factors.

We have a concentration of sales to and accounts receivable from several large retail customers

Although we have a broad range of retail customers that includes many national chain, regional, specialty and local retail stores, our five largest customers accounted for a significant percentage of our sales, approximately 48% and 58% of total revenues for Fiscal 2015 and 2014, respectively. In addition, retail customers comprising the five largest accounts receivable balances represented 60% and 67% of total accounts receivable balances at December 31, 2015 and 2014, respectively. We extend credit to retail customers based upon an evaluation of their financial condition and credit history, and collateral is not generally required. If one or more of these large retail customers cannot pay, the write-off of their accounts receivable could have a material adverse effect on our operations and financial condition. The loss of sales to any one or more of these large retail customers would also have a material adverse effect on our financial condition, results of operations and cash flows.

Retail customer's strategic business plans may negatively influence the distribution of our products to consumer

Changes in our retail and distribution customers strategic business plans including, but not limited to, (i) expansions, mergers, and/or consolidations, (ii) retail shelf space allocations for products within each outlet and in particular the cough/cold category in which we compete, (iii) changes in their private label assortment and (iv) product selections, distribution allocation, merchandising programs, commercial terms and retail pricing of our products as well as competitive products could affect the consumer sales of our products and result in a material adverse effect to our business and financial condition.

Our future success depends on the continued sales of our principal product

For Fiscal 2015 and 2014, our health care and cold remedy products, principally Cold-EEZE®, represented approximately 90% and 95%, respectively, of our total sales. Accordingly, we depend on the continued acceptance of Cold-EEZE® products by our customers. Our investments in and strategies used for our brand marketing are critical to achieve brand awareness with current consumers, educate potential new consumers and convert potential consumers into customers. However, there can be no assurance that Cold-EEZE® products will continue to receive, maintain or increase market acceptance. The inability to successfully commercialize Cold-EEZE® products in the future and/or expand the product line, for any reason, would have a material adverse effect on our financial condition, prospects and ability to continue operations.

Our products and potential new products are or may be subject to extensive governmental regulation

Our business is regulated by various agencies of the states and localities where our products are sold. Governmental regulations in foreign countries where we plan to commence or expand sales may prevent or delay entry into a market or prevent or delay the introduction, or require the reformulation of certain of our products. In addition, no prediction can be made as to whether new domestic or foreign legislation regulating our activities will be enacted. Any new legislation could have a material adverse effect on our business, financial condition and operations. Non-compliance with any applicable requirements may subject us or the manufacturers of our products to agency action, including warning letters, fines, product recalls, seizures and injunctions.

The manufacturing, processing, formulation, packaging, labeling and advertising of our health care and cold remedy products are subject to regulation by several federal agencies, including (i) the FDA, (ii) the Federal Trade Commission ("FTC"), (iii) the Consumer Product Safety Commission, (iv) the United States Department of Agriculture, (v) the United States Postal Service, (vi) the United States Environmental Protection Agency and (vii) the United States Occupational Safety and Health Administration.

In addition to OTC and prescription drug products, the FDA regulates the safety, manufacturing, labeling and distribution of dietary supplements, including vitamins, minerals and herbs, food additives, food supplements, over-the-counter and prescription drugs and cosmetics. The FTC also has overlapping jurisdiction with the FDA to regulate the promotion and advertising of vitamins, over-the-counter drugs, cosmetics and foods. In addition, our cold remedy products are homeopathic remedies which are subject to standards established by the Homeopathic Pharmacopoeia of the United States ("HPUS"). HPUS sets the standards for source, composition and preparation of homeopathic remedies which are officially recognized under the Federal Food, Drug and Cosmetics Act, as amended.

Preclinical development, clinical trials, product manufacturing, labeling, distribution and marketing of potential new products are also subject to federal and state regulation in the United States and other countries. Clinical trials and product marketing and manufacturing are subject to the rigorous review and approval processes of the FDA and foreign regulatory authorities. To obtain approval of a new drug product, a company must demonstrate through adequate and well-controlled clinical trials that the drug product is safe and effective for its intended use. Obtaining FDA and other required regulatory approvals is lengthy and expensive. Typically, obtaining regulatory approval for pharmaceutical products requires substantial resources and takes several years. The length of this process depends on the type, complexity and novelty of the product and the nature of the disease or other indication to be treated. Preclinical studies must comply with FDA regulations. Clinical trials must also comply with FDA regulations to ensure safety of the human subjects in the trial and may require large numbers of test subjects, complex protocols and possibly lengthy follow-up periods. Consequently, satisfaction of government regulations may take several years: may cause delays in introducing potential new products for considerable periods of time and may require imposing costly procedures upon our activities. If regulatory approval of new products is not obtained in a timely manner or not at all, we could be materially adversely affected. Even if regulatory approval of new products is obtained, such approval may impose limitations on the indicated uses for which the products may be marketed which could also materially adversely affect our business, financial condition and future operations.

We have a history of losses and limited working capital

We have experienced net losses for each of the four of the past five fiscal years. There can be no assurance that our strategic focus will result in any revenue growth or that we will be successful in initiating or acquiring any new lines of business, or that any such new lines of business will achieve profitability. As of December 31, 2015, we had working capital of approximately \$7.3 million which we believe is an acceptable and adequate level of working capital to support our business for at least the next twelve months ending March 31, 2017. Our ability to fund working capital and debt service needs will depend on our ability to generate cash in the future.

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change net operating loss carryforwards, or NOLs, to offset future taxable income. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs reflected on our balance sheet, even if we attain profitability.

Our success is dependent on key personnel

Our success depends, in part, upon the continued service of key personnel, such as Mr. Ted Karkus, Chairman and Chief Executive Officer, Mr. Robert V. Cuddihy, Jr., Chief Operating Officer and Chief Financial Officer, and certain managers and strategists within the Company. If we are unable to attract and retain such personnel, the loss of the services of any one of them could have a material adverse effect on us.

In order to be successful, we must retain and motivate executives and other key employees, including those in managerial, technical, marketing and health product positions. In particular, our product generation efforts depend on hiring and retaining qualified health and science professionals. Competition for skilled employees who can perform the services that we require is intense and hiring, training, motivating, retaining and managing employees with the skills required is time-consuming and expensive. If we are not be able to hire sufficient professional staff to support our operations, or to train, motivate, retain and manage the employees we do hire, it could have a material adverse effect on our business operations or financial results.

We are dependent on our manufacturing facility and suppliers for certain of our cold remedy products

Our manufacturing, warehousing and distribution center is located in Lebanon, Pennsylvania. In the event of a disruption of this facility, we would need to outsource to third parties, at least temporarily, our manufacturing, warehousing and distribution requirements. While such secondary sources have been identified for our products, if we are unable to find other sources or there were a delay in the ramp-up for the production and distribution operations for some of our products, it could have a material adverse effect on our operations.

Certain raw material active ingredients used in connection with the Cold-EEZE® products are purchased from a single unaffiliated supplier. Should the relationship terminate or the vendor become unable to supply material, we believe that current contingency plans would prevent such termination from materially affecting our operations, although there may be delays in production of our products until an acceptable replacement supplier is located.

Our inability to find alternative sources for some of our manufacturing and raw materials may have a material adverse effect on our operations and financial condition. In addition, the terms on which manufacturers and suppliers will make products and raw materials available to us could have a material effect on our success.

The manufacturing of OTC products and dietary supplements is subject to applicable current good manufacturing practice ("cGMP") regulations and FDA inspections. We believe we are in substantial compliance with material provisions of the applicable cGMP regulations. Contract manufacturers are also subject to these same requirements and we require such compliance in our contractual relationships with such manufacturers. However, we cannot assure that the FDA will agree with our determination of compliance. If the FDA disagrees, it could, upon inspection of our facility, issue a notice of violations, referred to as a form FDA-483, or issue a Warning Letter, or both. If the FDA concludes that there is an imminent public health threat or if we fail to take timely corrective actions to the satisfaction of the FDA, the agency can initiate legal actions, such as seizure and injunction, which could include a recall order or the entry of a consent decree, or both. In addition, we could be subject to monetary penalties and even criminal prosecution for egregious conduct. The FDA could initiate similar legal actions against the contract manufacturer if it concludes its facility is not in compliance, which would affect the availability of our products. While secondary sources have been identified for our products, our inability to find other sources or a delay in the ramp-up for the production and distribution operations for some of its products may have a material adverse effect on our operations.

We are uncertain as to whether we can protect our proprietary rights

The strength of our patent position and proprietary formulations and compounds may be important to our long-term success. We currently own numerous U.S. and foreign patents in connection with potential products; however there can be no assurance that these patents and proprietary formulations and compounds will effectively protect our products from duplication by others. In addition, we may not be able to afford the expense of any litigation which may be necessary to enforce our rights under any of the patents. Furthermore, there can be no assurance that third parties will not obtain access to or independently develop our technologies, know-how, ideas, concepts and documentation, which could have a material adverse effect on our financial condition.

Although we believe that current and future products do not and will not infringe upon the patents or violate the proprietary rights of others, if any of our current or future products do infringe upon the patents or proprietary rights of others, we may have to modify the products or obtain an additional license for the manufacture and/or sale of such products. We could also be prohibited from selling the infringing products. If we were found to infringe on the proprietary rights of others, it is uncertain whether we would be able to take corrective actions in a timely manner, upon acceptable terms and conditions, or at all, and the failure to do so could have a material adverse effect upon our business, financial condition and operations.

Our existing products and potential new products expose us to potential product liability claims

Our business results in exposure to an inherent risk of potential product liability claims, including claims for serious bodily injury or death caused by the sales of our existing products and the products which are being developed. These claims could lead to substantial damage awards. While we currently maintain product liability insurance, a successful claim brought against us in excess of, or outside of, existing insurance coverage could have a material adverse effect on our results of operations and financial condition. Claims against us, regardless of their merit or eventual outcome, may also have a material adverse effect on the consumer demand for our products.

We are involved in litigation matters

We are, from time-to-time, subject to various legal proceedings and claims, either asserted or unasserted. Any such claims, whether with or without merit, can be time-consuming and expensive to defend and can divert management's attention and resources. Furthermore, there is no assurance that the outcome of all current or future litigation will not have a material adverse effect on us.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers.

In addition, the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley") and the related rules of the Securities and Exchange Commission require that we maintain effective internal control over financial reporting and disclosure controls and procedures. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall.

Our compliance with Section 404 of Sarbanes-Oxley may require that we incur substantial expense and expend significant management time on compliance related issues. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock would likely decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our stock price is volatile

The market price of our Common Stock has experienced significant volatility. From January 1, 2015 to March 25, 2016, the closing price of our stock has ranged from \$1.16 to \$1.71 per share. There are several factors which could affect the price of our Common Stock, including announcements of technological innovations for new commercial products by us or our competitors, developments concerning propriety rights, new or revised governmental regulation or general conditions in the market for our products. Sales of a substantial number of shares by existing stockholders could also have an adverse effect on the market price of our Common Stock.

Future sales of shares of our Common Stock in the public market could adversely affect the trading price of shares of the Common Stock and our ability to raise funds in new stock offerings

Future sales of substantial amounts of shares of our Common Stock in the public market, or the perception that such sales are likely to occur, could affect prevailing trading prices of our Common Stock. As of March 25, 2016, we had 17,080,776 shares of Common Stock outstanding.

As of March 25, 2016, there are outstanding options, which are fully vested, to purchase an aggregate of 1,709,250 shares of our Common Stock at an average exercise price of \$1.21 per share. If these options are exercised, and the holders of these options were to attempt to sell a substantial amount of their holdings at once, the market price of our Common Stock would likely decline. Moreover, the perceived risk of this potential dilution could cause stockholders to attempt to sell their shares and investors to "short" our stock, a practice in which an investor sells shares that he or she does not own at prevailing market prices, hoping to purchase shares later at a lower price to cover the sale. As each of these events would cause the number of shares of Common Stock being offered for sale to increase, our Common Stock's market price would likely further decline. All of these events could combine to make it very difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

Our Common Stock may be delisted from The NASDAQ Global Market, which would adversely affect the price and liquidity of our Common Stock

Our Common Stock is currently listed on The NASDAQ Global Market. If our Common Stock is delisted, it could reduce the price of our Common Stock and the levels of liquidity available to our stockholders. In addition, the delisting of our Common Stock could materially adversely affect our access to the capital markets, and any limitation on liquidity or reduction in the price of our Common Stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from The NASDAQ Global Market could also result in other negative implications, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

If securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline

The trading market for our Common Stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, products or stock performance, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, the unpredictability of our financial results likely reduces the certainty, and therefore reliability, of the forecasts by securities or industry analysts of our future financial results, adding to the potential volatility of our stock price.

Our officers and directors own a substantial amount of our Common Stock

As of March 25, 2016, our executive officers and directors beneficially owned approximately 30.0% of our Common Stock. These individuals have significant influence over the outcome of all matters submitted to stockholders for approval, including the election of directors. Consequently, they exercise substantial influence over all major decisions including major corporate actions such as mergers and other business combinations transactions which could result in or prevent a change of control of the Company. Circumstances may occur in which the interests of our officers and directors could be in conflict with the interests of other shareholders. Accordingly, a shareholder's ability to influence us through voting their shares may be limited or the market price of our Common Stock may be adversely affected.

We do not intend to pay cash dividends in the foreseeable future

We have not paid cash dividends on our Common Stock since our inception. Our intention is to retain earnings, if any, for use in the business and we do not anticipate paying any cash dividends to stockholders in the foreseeable future.

Our Certificate of Incorporation and By-laws contain certain provisions that may be barriers to a takeover

Our Certificate of Incorporation and By-laws contain certain provisions which may deter, discourage, or make it difficult for another person or entity to gain control of the Company through a tender offer, merger, proxy contest or similar transaction or series of transactions. These provisions may deter a future tender offer or other takeover attempt which could include a premium over the market price of our Common Stock at the time. Such provisions could depress the trading price of our Common Stock

We have agreed to indemnify our Officers and Directors from liability

Our Certificate of Incorporation and our By-laws provide that we will indemnify, to the fullest extent permitted by the Delaware General Corporation Law, any person who is or was made a party to, or is or was threatened to be made a party to, any pending, completed, or threatened action, suit or proceeding because he or she is or was a director, officer, employee or agent of the Company or is or was serving at the Company's request as a director, officer, employee or agent of any corporation, partnership, joint venture, trust or other enterprise. These provisions permit us to advance expenses to an indemnified party in connection with defending any such proceeding, upon receipt of an undertaking by the indemnified party to repay those amounts if it is later determined that the party is not entitled to indemnification. We entered into indemnity agreements with each member of our board of directors and Mr. Cuddihy. These agreements provide, among other things, that we will indemnify each officer and director in the event they become a party or otherwise a participant in any action or proceeding on account of their service as a director or officer of the Company (or service for another corporation or entity in any capacity at the request of the Company) to the fullest extent permitted by applicable law. These indemnity provisions may reduce the likelihood of derivative litigation against directors and officers and discourage or deter stockholders from suing directors or officers for breaches of their duties to the Company, even though such an action, if successful, might otherwise benefit the Company or its stockholders. In addition, to the extent that we expend funds to indemnify directors and officers, funds will be unavailable for operational purposes.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters is located in Doylestown, Pennsylvania. We purchased this property in 1998. Our headquarters is approximately 13,000 square feet and is comprised of office space and a storage area. Our principal manufacturing facility is located in Lebanon, Pennsylvania. The facility was purchased in October 2004. The facility has a total area of approximately 57,500 square feet, comprised of manufacturing, warehousing and office space. We believe that our existing facilities are adequate at this time and do not anticipate the need for additional facilities in the foreseeable future.

Item 3. Legal Proceedings

<u>PROPHASE LABS, INC. PROPHASE LABS, INC. FOR THE BENEFIT OF PHUSION LABORATORIES, LLC vs. Phosphagenics, Inc., Phosphagenics, LTD and Phusion Laboratories, LLC as a nominal defendant</u>

On October 17, 2014, we initiated a demand for arbitration with the American Arbitration Association, case number 01-14-0001-7373. This demand for arbitration pertains to our Phusion joint venture and the matter is against Phosphagenics, Inc. and Phosphagenics LTD (collectively known as the "Phosphagenics Entities"). We have raised certain claims based upon the Phosphagenics Entities alleged breach of a certain amended and restated license agreement for the exploitation of certain intellectual property and, separately, breach of the Phusion joint venture operating agreement as between the Company and the Phosphagenics Entities. The Phosphagenics Entities have made counter claims of breaches against the Company and Phusion. The arbitration hearing was held during December 2015 and January 2016 and the evidentiary hearing is now concluded. Each of the parties submitted to the arbitrator their post-hearing briefs on or before March 15, 2016. At this time, no prediction as to the outcome of this action can be made, and we anticipate an arbitral ruling will likely be rendered in or about June 2016.

Other Litigation

In the normal course of our business, we are named as defendant in legal proceedings. It is our policy to vigorously defend litigation and/or enter into settlements of claims where management deems appropriate.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our Common Stock is currently traded on The NASDAQ Global Market under the trading symbol "PRPH." The price set forth in the following table represents the high and low closing bid prices for our Common Stock for each quarter of the Fiscal 2015 and 2014, as reported on The NASDAQ Global Market.

Common Stock

		20			2014				
Quarter Ended		High		Low		High		Low	
March 31,	\$	1.67	\$	1.30	\$	2.25	\$	1.66	
June 30,	\$	1.42	\$	1.23	\$	2.05	\$	1.50	
September 30,	\$	1.71	\$	1.33	\$	1.68	\$	1.38	
December 31,	\$	1.62	\$	1.20	\$	1.50	\$	1.25	

Holders

As of March 16, 2016, there were approximately 219 holders of record of our Common Stock, including brokerage firms, clearing houses, and/or depository firms holding the Company's securities for their respective clients. The exact number of beneficial owners of our securities is not known but exceeds 400.

Dividends

We have not declared, nor paid any cash dividends on our Common Stock since our Company's inception. At this time, we intend to retain our earnings to finance future growth and maintain liquidity. Future cash dividends, if any, will be at the discretion of our Board of Directors and will depend upon, among other things, our future operations and earnings, capital requirements, general financial condition, contractual and financing restrictions and such other factors as our Board of Directors may deem relevant.

Warrants and Options

In addition to our outstanding Common Stock, there were reserved for issuance 1,760,250 shares of our Common Stock underlying outstanding unexercised and vested options and Warrants as of December 31, 2015 at the price-per-share stated and expiration date indicated, as follows:

Description	Number of Options	Exercise Price		Expiration Date
Option Plan	935,000	\$	1.00	December 14, 2017
Option Plan	75,000	\$	1.08	May 28, 2018
Option Plan	20,000	\$	0.87	November 5, 2018
Warrants	51,000	\$	1.35	December 10, 2018
Option Plan	100,000	\$	1.17	December 18, 2018
Option Plan	405,500	\$	1.65	December 18, 2019
Option Plan	15,000	\$	1.36	December 20, 2019
Option Plan	11,250	\$	1.48	April 9, 2020
Option Plan	147,500	\$	1.39	April 20, 2020
Total	1,760,250			

Securities Authorized Under Equity Compensation

The following table sets forth certain information regarding stock option and warrant grants made to employees, directors and consultants:

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

	Number of		Number of Securities
	Securities to be	Weighted	Remaining Available for
	Issued Upon	Average	Future Issuance Under Equity
	Exercise of	Exercise Price	Compensation Plans
	Outstanding	of Outstanding	(Excluding Securities
	Options	Options	Reflected in Column A)
Plan Category	(A)	(B)	(C)
(12)			
Equity Plans Approved by Security Holders (1,2)	1 713 000	S 1.21	167 467

- (1) On May 5, 2010, our shareholders approved the 2010 Equity Compensation Plan, which was subsequently amended, restated and approved by shareholders on April 24, 2011 and further amended and approved by our shareholders on May 6, 2013 (the "2010 Plan"). The 2010 Plan provides that the total number of shares of Common Stock that may be issued is equal to 2.5 million shares, including 900,000 shares that were authorized for issuance but unissued under a 1997 incentive stock option plan ("1997 Plan). All of our employees, including employees who are officers or members of the Board are eligible to participate in the 2010 Plan. Consultants and advisors who perform services for us are also eligible to participate in the 2010 Plan. At December 31, 2015, we have outstanding 1,713,000 stock options, subject to vesting, under the 2010 Plan. For Fiscal 2015, we charged to operations \$135,000 for compensation expense for the fair value of the vested portion of the stock options (see Note 6 to Notes to Consolidated Financial Statements). At December 31, 2015, there are 19,659 shares of Common Stock that may be issued in the future pursuant to the 2010 Plan.
- (2) On May 5, 2010, our shareholders approved the 2010 Directors' Equity Compensation Plan which was subsequently amended and approved by our shareholders on May 6, 2013. The 2010 Directors' Equity Compensation Plan provides that the total number of shares of Common Stock that may be issued under the 2010 Directors' Equity Compensation Plan is equal to 425,000. For Fiscal 2015 there were no shares of our Common Stock granted under the 2010 Directors' Equity Compensation Plan. At December 31, 2015, there are 147,808 shares of Common Stock that may be issued pursuant to the 2010 Directors Equity Compensation Plan.

2014 Equity Line of Credit

On May 28, 2014 we entered into an equity line of credit agreement (such arrangement, the "2014 Equity Line") with Dutchess whereby Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,000,000 shares of the Company's Common Stock, over a period of 36 months from the effectiveness of the registration statement registering the resale of shares purchased by Dutchess pursuant to the 2014 Equity Line. On May 29, 2014, we filed a registration statement with the SEC to register for sale up to 3,000,000 shares of our Common Stock and the registration statement was declared effective by the SEC on June 4, 2014.

In June 2015, we sold an aggregate of 438,480 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of \$524,000. During the period June 4, 2014 through September 30, 2014, we sold an aggregate of 2,561,520 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of \$3.7 million. The sales of the shares under the 2014 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended in reliance upon Section 4(a)(2) (or Regulation D promulgated thereunder). At June 30, 2015, there were no shares of our Common Stock available for sale under the terms of the 2014 Equity Line. As a consequence of the utilization of the 2014 Equity Line, on July 23, 2015 we filed a post-effective amendment to the underlying registration statement for the 2014 Equity Line to terminate the registration statement.

2015 Equity Line of Credit

On July 30, 2015, we entered into the 2015 Equity Line with Dutchess. Pursuant to the 2015 Equity Line, Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,200,000 shares of our Common Stock, over a period of 36 months from the effectiveness of the registration statement registering the resale of shares purchased by Dutchess pursuant to the Investment Agreement.

We may, at our discretion, draw on the 2015 Equity Line from time to time, as and when we determine appropriate in accordance with the terms and conditions of the 2015 Equity Line. The maximum number of shares that we are entitled to put to Dutchess in any one draw down notice shall not exceed 500,000 shares with a purchase price calculated in accordance with the 2015 Equity Line. We may deliver a notice for a subsequent put from time to time, following the one day pricing period for the prior put.

The purchase price shall be set at ninety-five percent (95%) of the volume weighted average price (VWAP) of the Common Stock during the one trading day immediately following our put notice. We have the right to withdraw all or any portion of any put, except that portion of the put that has already been sold to a third party, including any portion of a put that is below the minimum acceptable price set forth on the put notice, before the closing. In the event Dutchess receives more than a five percent (5%) return on the net sales for a specific put, Dutchess must remit such excess proceeds to us; however, in the event Dutchess receives less than a five percent (5%) return on the net sales for a specific put, Dutchess will have the right to deduct from the proceeds of the put amount on the applicable closing date so Dutchess's return will equal five percent (5%).

There are put restrictions applied on days between the draw down notice date and the closing date with respect to that particular put. In addition, Dutchess will not be obligated to purchase shares if Dutchess' total number of shares beneficially held at that time would exceed 4.99% of the number of shares of Common Stock as determined in accordance with Rule 13d-1(j) of the Securities Exchange Act of 1934, as amended. In addition, we are not permitted to draw on the facility unless there is an effective registration statement to cover the resale of the shares.

Pursuant to the terms of the 2015 Equity Line, we are obligated to file one or more registrations statements with the SEC to register the resale by Dutchess of the shares of Common Stock issued or issuable under the 2015 Equity Line. In addition, we are obligated to use all commercially reasonable efforts to have the registration statement declared effective by the SEC within 90 days after the registration statement is filed. On August 4, 2015, we filed a registration statement for the underlying shares of the 2015 Equity Line with the SEC and the registration statement was declared effective by the SEC on August 21, 2015.

During the period August 21, 2015 through December 31, 2015, we sold an aggregate of 750,000 shares of Common Stock to Dutchess under and pursuant to the 2015 Equity Line and we derived net proceeds of \$1.0 million. The sales of the shares under the 2015 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended in reliance upon Section 4(2) (or Regulation D promulgated thereunder). At December 31, 2015 we have 2,450,000 shares of our Common Stock available for sale, at our discretion, under the terms of the 2015 Equity Line and covered pursuant to a registration statement.

Item 6. Selected Financial Data

The following table sets forth the selected financial data appearing in or derived from our consolidated financial statements for and at the end of the years ended December 31, 2015, 2014, 2013, 2012 and 2011. The selected financial data should be read in conjunction with the consolidated financial statements appearing elsewhere herein, and with Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations (in thousands, except per share amounts):

	Year Ended December 31,									
	2015 2014					2013	2012			2011
Statement of Income Data:										
Net sales	\$	20,604	\$	22,070	\$	25,032	\$	22,406	\$	17,453
Gross profit	\$	12,178	\$	14,179	\$	16,671	\$	14,252	\$	11,282
Income (loss) from operations before taxes	\$	(3,600)	\$	(7,834)	\$	405	\$	(1,091)	\$	(2,710)
Net income (loss)	\$	(3,600)	\$	(7,834)	\$	405	\$	(1,091)	\$	(2,710)
Basic income (loss) per share	\$	(0.22)	\$	(0.47)	\$	0.03	\$	(0.07)	\$	(0.18)
Diluted income (loss) per share	\$	(0.22)	\$	(0.47)	\$	0.03	\$	(0.07)	\$	(0.18)
Weighted average shares outstanding:		17.200		17.772		15.020		14.042		14.017
Basic		16,398		16,773		15,839		14,843		14,817
Diluted		16,398		16,773		16,276		14,843		14,817
				A	As of l	December 31	l ,			
		2015		2014		2013		2012		2011
Balance Sheet Data:										
Working capital	\$	7,345	\$	8,217	\$	6,655	\$	5,809	\$	5,342
Total assets	\$	14,829	\$	16,057	\$	17,420	\$	16,661	\$	19,079
Long term debt and other obligations	\$	1,466	\$	100	\$	200	\$	300	\$	-
Stockholders' equity	\$	8,829	\$	10,716	\$	12,596	\$	11,451	\$	11,226
		-	- 21 -							

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Our Business. We are a manufacturer, marketer and distributor of a diversified range of homeopathic and health care products that are offered to the general public. We are also engaged in the research and development of potential natural based health products along with supplement and cosmeceutical products.

Our primary business is the manufacture, distribution, marketing and sale of OTC health care and cold remedy products to consumers through national chain, regional, specialty and local retail stores. Our flagship brand is Cold-EEZE® and our principal product is Cold-EEZE® cold remedy zinc gluconate lozenges, proven in clinical studies to reduce the duration and severity of symptoms of the common cold. In addition to Cold-EEZE® cold remedy lozenges, we market and distribute non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE® cold remedy QuickMelts® and (ii) Cold-EEZE® cold remedy Oral Spray. Each of our Cold-EEZE® QuickMelts® products are based on our proprietary zinc gluconate formulation in combination with certain natural (i) immune system support, (ii) energy, (iii) sleep and relaxation, and/or (iv) cold and flu symptom relieving active ingredients. In Fiscal 2015, we introduced three new Cold-EEZE® product line extensions (see Product Development below). We also manufacture, market and distribute organic cough drops and a Vitamin C supplement, and perform contract manufacturing services of cough drop and other OTC cold remedy products for third parties.

Product Development

Our flagship Cold-EEZE® brand has generally performed well within the cough-cold category over the past several years. We began shipping in the third quarter of Fiscal 2015 three new Cold-EEZE® product line extensions: (i) a Cold-EEZE® Multi-Symptom Relief for Cold and Flu lozenge, (ii) a Cold-EEZE® Daytime and Nighttime Multi-Symptom Relief in liquid form for each of adults and children, and (iii) Cold-EEZE® Natural Allergy Relief caplets for indoor and outdoor allergies.

Although we continue to expand our Cold-EEZE® product offerings, some retailers are limiting and/or reallocating shelf and promotional space away from the cough-cold category to other product categories. With cough-cold shelf and promotional space at a premium, opportunities in the future to introduce new Cold-EEZE® products in the cough-cold category may be limited. Therefore, to continue to grow our Company, we are in the process of implementing a series of new product development and pre-commercialization initiatives in the dietary supplement category.

Initial dietary supplement product development activities were completed in the fourth quarter of Fiscal 2015 under the brand name of TK SupplementsTM. The inaugural TK SupplementsTM product line is comprised of three men's health products: (i) Legendz XLTM for sexual health, (ii), Triple Edge XLTM, a daily energy booster plus testosterone support, and (iii) Super ProstaFlow *Plus*TM for prostate and urinary health. The first of these three TK SupplementsTM products, Legendz XLTM is scheduled for launch in the first half of Fiscal 2016.

While management anticipates the growth potential in this category may be better, the risks associated with introducing new products that do not leverage the Cold-EEZE® brand name may be higher. Therefore, no assurance can be made that our new product efforts will be successful.

Secured Promissory Notes

On December 11, 2015, we executed two Subscription Agreements (the "Subscription Agreements") with the investors named therein (the "Investors") providing for the purchase of 12% Secured Promissory Notes – Series A ("Notes") in the aggregate principal amount of up to \$3.0 million and warrants to purchase shares of our Common Stock (the "Warrants"). The Warrants grant the Investors the right to purchase 17,000 shares of common stock for every \$500,000 of principal amount of Notes purchased by the Investors

Notes in the amount of \$1,500,000 and 51,000 Warrants, at an exercise price of \$1.35 per share, which is equal to the closing price of our Common Stock on the date of investment, were issued by the Company and its wholly-owned subsidiaries Pharmaloz Manufacturing Inc. and Quigley Pharma Inc. (collectively, the "Obligors") and funded on December 11, 2015.

The Notes are secured by all of our tangible and intangible assets. The Notes bear interest at the rate of 12% per annum, payable semi-annually and the principal is due and payable on June 15, 2017. The Notes may be pre-paid at any time prior to maturity without penalty. The effective interest, inclusive of the Warrants and loan origination costs, is 14.3% per annum. The net proceeds from the Notes will be used for general working capital.

In connection with the issuance of the Notes, we entered into a security agreement with John E. Ligums, Jr., an Investor and a shareholder in the Company, as collateral agent for the Investors (the "Security Agreement") to secure the timely payment and performance in full of the Obligors' obligations under the Notes. Under the Security Agreement, the Obligors grant to the Collateral Agent, for the benefit of the Investors a lien upon and security interest in the property and assets listed as collateral in the Security Agreement, including without limitation, all of the Obligors' personal property, inventory, equipment, general intangibles, cash and cash equivalents, and proceeds.

Seasonality of the Business

Our net sales are derived principally from our OTC health care and cold remedy products. Currently, our sales are influenced by and subject to fluctuations in the timing of purchase and the ultimate level of demand for our products which are a function of the timing, length and severity of each cold season. Generally, a cold season is defined as the period of September to March ("Cold Season") when the incidence of the common cold and flu rises as a consequence of the change in weather and other factors. We generally experience in the third and fourth quarter higher levels of net sales along with a corresponding increase in marketing and advertising expenditures designed to promote our products during the cold season. Revenues and related marketing costs are generally at their lowest levels in the second quarter when consumer demand generally declines. We track health and wellness trends and develop retail promotional strategies to align our production scheduling, inventory management and marketing programs to optimize consumer purchases.

Income Taxes

As of December 31, 2015, we have net operating loss carry-forwards of approximately \$44.5 million for federal purposes that will expire beginning in Fiscal 2020 through 2034. Additionally, there are net operating loss carry-forwards of \$21.9 million for state purposes that will expire beginning in Fiscal 2020 through 2034. Until sufficient taxable income to offset the temporary timing differences attributable to operations, and the tax deductions attributable to option, warrant and stock activities are assured, a valuation allowance equaling the total deferred tax asset is being provided. As a consequence of the accumulated losses of the Company, we believe that this allowance is required due to the uncertainty of realizing these tax benefits in the future.

Results of Operations

Fiscal 2015 compared with Fiscal 2014

Net sales for Fiscal 2015 decreased \$1.5 million, or 6.6%, to \$20.6 million as compared to \$22.1 million for Fiscal 2014. The decrease in net sales from Fiscal 2014 to Fiscal 2015 is due principally to the net effects of (i) the timing of customer purchases, product mix shipped from period to period and lower consumer demand as a consequence of several factors including the decreased incidence and severity of upper respiratory illnesses, from period to period, offset by (ii) an increase of \$1.0 million in our contract manufacturing operations from non-related third party entities to produce lozenge-based products. According to IMS Health (a healthcare industry information provider), key industry statistics reveal that the incidence of upper respiratory illness across the country has been down 12.6% for the period September through December 2015 as compared to the prior year September through December 2014. The category of cough and cold product sales, including our Cold-EEZE® sales, are highly correlated to the incidence of upper respiratory illness.

Cost of sales for Fiscal 2015 were \$8.4 million as compared to \$7.9 million for Fiscal 2014. For Fiscal 2015 and Fiscal 2014, we realized a gross margin of 59.1% and 64.2%, respectively. The decrease of 5.1% in gross margin from the prior period is principally due to (i) a reduction in the absorption of fixed production costs, (ii) fluctuations in our product mix shipped from period to period and (iii) an increase in contract manufacturing net sales which carry lower gross margins. Gross margins are generally influenced by fluctuations in quarter-to-quarter production volume, fixed production costs and related overhead absorption, raw ingredient costs, inventory mark to market write-downs, if any, retail cooperative incentive promotion and the timing of shipments to customers which are factors of the seasonality of our sales activities and products.

Sales and marketing expense for Fiscal 2015 decreased \$1.3 to \$7.7 million as compared to \$9.0 million for Fiscal 2014. The decrease in sales and marketing expense for Fiscal 2015 as compared to Fiscal 2014 was principally due to a decrease in advertising expenditures as we managed the scope and timing of our media and product promotion advertising campaigns from period to period.

General and administrative ("G&A") expenses decreased \$1.1 million for Fiscal 2015 to \$7.0 million as compared to \$8.1 million in Fiscal 2014. The decrease in G&A expense for Fiscal 2015 as compared to Fiscal 2014 was principally due to a decrease in professional and legal fees related to certain, now resolved, litigation matters, and in corporate personnel expenses.

Research and development costs for Fiscal 2015 and 2014 were \$1.1 million and \$1.3 million, respectively. The decrease of \$244,000 in research and development costs for Fiscal 2015 as compared to Fiscal 2014 was principally due a decrease in the scope, timing, cost and amount of research and development activity from period to period. Additionally, we continue to engage in other research and development activities that we determine are appropriate and we may increase our research and development activities in future periods.

Interest income and expense for Fiscal 2015 was \$2,000 and \$18,000, respectively, as compared to \$4,000 and \$10,000, respectively for Fiscal 2014. The decline in interest income in Fiscal 2015 as compared to Fiscal 2014 is due principally to lower invested cash balances from period to period. The increase in interest expense for Fiscal 2015 as compared to Fiscal 2014 was due principally to the interest expense incurred pursuant to the issuance of the Notes in December 2015.

As noted above, we have net operating loss carry-forwards for both federal and certain states. As a consequence of these loss carry-forwards, we did not incur income tax expense for Fiscal 2015 or Fiscal 2014.

As a consequence of the effects of the above, the net loss for Fiscal 2015, was \$3.6 million, or (\$0.22) per share, as compared to a net loss of \$7.8 million, or (\$0.47) per share, for Fiscal 2014.

Fiscal 2014 compared with Fiscal 2013

Net sales for Fiscal 2014 decreased \$2.9 million, or 11.8%, to \$22.1 million as compared to \$25.0 million for Fiscal 2013. The decrease in net sales from Fiscal 2013 to Fiscal 2014 is principally due to the net effects of (i) a reduction in promotional display programs shipped due principally to certain retail customers reducing their allocation of display space for the cough-cold category, (ii) an increase in our cooperative incentive promotion and coupon costs, which are recorded as a reduction to our revenues, offset by (iii) an increase in shipments of our QuickMelts® products. In addition, net sales of our contract manufacturing operations decreased \$433,000 in Fiscal 2014 to \$1.4 million as compared to \$1.8 million in Fiscal 2013 due to fluctuations in contract manufacturing orders from non-related third party entities to produce lozenge-based products.

Cost of sales for Fiscal 2014 were \$7.9 million as compared to \$8.4 million for Fiscal 2013. For Fiscal 2014 and Fiscal 2013, we realized a gross margin of 64.2% and 66.6%, respectively. The decrease of 2.4% in gross margin from the prior period is principally due to (i) an increase in our cooperative incentive promotion and coupon costs and (ii) a reduction in the absorption of fixed production costs as a consequence of a decline in net sales, (iii) fluctuations in our product mix shipped from period to period and (iv) the initial expenses incurred as a consequence of a packaging transition to a slightly narrower package of our Cold-EEZE® Cold Remedy lozenges at certain retail accounts to obtain additional/new distribution of our Cold-EEZE® Cold Remedy QuickMelts® products for Fiscal 2014. Gross margins are principally influenced by fluctuations in quarter-to-quarter production volume, fixed production costs and related overhead absorption, raw ingredient costs, inventory mark to market write-downs, if any, retail cooperative incentive promotion and the timing of shipments to customers which are factors of the seasonality of our sales activities and products.

Sales and marketing expense for Fiscal 2014 decreased \$573,000 to \$9.0 million as compared to \$9.5 million for Fiscal 2013. The decrease in sales and marketing expense for Fiscal 2014 as compared to Fiscal 2013 was principally due to a decrease in advertising expenditures as we managed the scope and timing of our media and product promotion advertising campaigns from period to period. We continue to make significant, strategic marketing investments in an effort to build and grow the sales of our OTC cold remedy products.

General and administrative ("G&A") expenses increased \$2.2 million for Fiscal 2014 to \$8.1 million as compared to \$5.9 million in Fiscal 2013. The increase in G&A expense for Fiscal 2014 as compared to Fiscal 2013 was primarily due to an increase in professional and legal fees related to certain, now resolved, litigation matters, and in personnel expenses.

Research and development costs for Fiscal 2014 and 2013 were \$1.3 million and \$824,000, respectively. The increase of \$498,000 in research and development costs for Fiscal 2014 as compared to Fiscal 2013 was principally due an increase in the scope, timing, cost and amount of research and development activity from period to period. Additionally, we continue to engage in other research and development activities that we determine are appropriate and we may increase our research and development activities in future periods.

As a consequence of our impairment assessment, we determined that a full impairment occurred of the Phusion intangible asset, license technology. As a consequence, for Fiscal 2014 we charged to operation a \$3.6 million impairment charge.

Interest and other income for Fiscal 2014 and 2013 was \$4,000 and \$2,000 respectively. Interest expense for Fiscal 2014 was \$10,000 as compared to \$13,000 for Fiscal 2013 as a consequence of interest paid pursuant to the terms of the Godfrey Settlement Agreement consummated in December 2012.

As noted above, we have net operating loss carry-forwards for both federal and certain states. As a consequence of these loss carry-forwards, we did not incur income tax expense for Fiscal 2014 or Fiscal 2013.

As a consequence of the effects of the above, the net loss for Fiscal 2014, was \$7.8 million, or (\$0.47) per share, as compared to a net income of \$405,000, or \$0.03 per share, for Fiscal 2013.

Liquidity and Capital Resources

Our aggregate cash and cash equivalents as of December 31, 2015 were \$1.7 million as compared to \$2.9 million at December 31, 2014. Our working capital was \$7.3 million and \$8.2 million as of December 31, 2015 and December 31, 2014, respectively. Changes in our working capital for Fiscal 2015 is principally due to the net effect of (i) cash used in operations of \$3.5 million comprised principally of (a) net loss of \$3.6 million, (b) a decrease in accrued advertising of \$1.2 million, (c) increase to inventory of \$1.0 million offset by (d) decrease to accounts receivable of \$1.8 million, (ii) capital expenditures of \$718,000 and (iii) the installment payment of \$100,000 pursuant to the terms of the Godfrey Settlement Agreement, offset by (iv) net proceeds of \$1.6 million from the sales of our Common Stock and (v) proceeds of \$1.5 million from the Notes.

2014 Equity Line of Credit

On May 28, 2014, we entered into a equity line of credit agreement (such arrangement, the "2014 Equity Line") with Dutchess whereby Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,000,000 shares of our Common Stock, over a period of 36 months from the effectiveness of the registration statement registering the resale of shares purchased by Dutchess pursuant to the Investment Agreement. On May 29, 2014, we filed a registration statement with the SEC to register for sale up to 3,000,000 shares of our Common Stock and the registration statement was declared effective by the SEC on June 4, 2014.

During the period June 4, 2014 through September 30, 2014, we sold an aggregate of 2,561,520 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of \$3.7 million. In June 2015, we sold an aggregate of 438,480 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of \$524,000. The sales of the shares under the 2014 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended in reliance upon Section 4(a)(2) (or Regulation D promulgated thereunder). At June 30, 2015, there were no shares of our Common Stock available for sale under the terms of the 2014 Equity Line. As a consequence of the utilization of the 2014 Equity Line, on July 23, 2015 we filed a post-effective amendment to the underlying registration statement for the 2014 Equity Line to terminate the registration statement.

2015 Equity Line of Credit

On July 30, 2015, we entered into a new equity line of credit agreement (such arrangement, the "2015 Equity Line") with Dutchess. Pursuant to the 2015 Equity Line, Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,200,000 shares of our Common Stock, over a period of 36 months from the effectiveness of the registration statement registering the resale of shares purchased by Dutchess pursuant to the Investment Agreement.

We may, at our discretion, draw on the 2015 Equity Line from time to time, as and when we determine appropriate in accordance with the terms and conditions of the 2015 Equity Line. The maximum number of shares that we are entitled to put to Dutchess in any one draw down notice shall not exceed 500,000 shares with a purchase price calculated in accordance with the 2015 Equity Line. We may deliver a notice for a subsequent put from time to time, following the one day pricing period for the prior put.

The purchase price shall be set at ninety-five percent (95%) of the volume weighted average price (VWAP) of the Common Stock during the one trading day immediately following our put notice. We have the right to withdraw all or any portion of any put, except that portion of the put that has already been sold to a third party, including any portion of a put that is below the minimum acceptable price set forth on the put notice, before the closing. In the event Dutchess receives more than a five percent (5%) return on the net sales for a specific put, Dutchess must remit such excess proceeds to us; however, in the event Dutchess receives less than a five percent (5%) return on the net sales for a specific put, Dutchess will have the right to deduct from the proceeds of the put amount on the applicable closing date so Dutchess's return will equal five percent (5%).

There are put restrictions applied on days between the draw down notice date and the closing date with respect to that particular put. In addition, Dutchess will not be obligated to purchase shares if Dutchess' total number of shares beneficially held at that time would exceed 4.99% of the number of shares of Common Stock as determined in accordance with Rule 13d-1(j) of the Securities Exchange Act of 1934, as amended. In addition, we are not permitted to draw on the facility unless there is an effective registration statement to cover the resale of the shares.

Pursuant to the terms of the 2015 Equity Line, we are obligated to file one or more registrations statements with the SEC to register the resale by Dutchess of the shares of Common Stock issued or issuable under the 2015 Equity Line. In addition, we are obligated to use all commercially reasonable efforts to have the registration statement declared effective by the SEC within 90 days after the registration statement is filed. On August 4, 2015, we filed a registration statement for the underlying shares of the 2015 Equity Line with the SEC and the registration statement was declared effective by the SEC on August 21, 2015.

During the period August 21, 2015 through December 31, 2015, we sold an aggregate of 750,000 shares of our Common Stock to Dutchess under and pursuant to the 2015 Equity Line and we derived net proceeds of \$1.0 million. The sales of the shares under the 2015 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended in reliance upon Section 4(2) (or Regulation D promulgated thereunder). At December 31, 2015 we have 2,450,000 shares of our Common Stock available for sale, at our discretion, under the terms of the 2015 Equity Line and covered pursuant to a registration statement.

As a consequence of the seasonality of our business, we realize variations in operating results and demand for working capital from quarter to quarter. As of December 31, 2015, we had working capital of approximately \$7.3 million and 2,450,000 shares of Common Stock available for sale under the 2015 Equity line. We believe our current working capital and available equity line of credit and an available \$1.5 million in additional debt financing through the Subscription Agreements is an acceptable and adequate level of working capital to support our business for at least the next twelve months ending March 31, 2017.

Our future contractual obligations and commitments at December 31, 2015 consist of the following (in thousands):

Year	Emp	2015 ployment entracts	Godfrey Settlement Agreement		Settlement Agreement		 Notes	Total
2016	\$	1,025	\$	100	\$ 	\$ 1,125		
2017		1,025		-	1,500	2,525		
2018		512		-		512		
2019		_				_		
2020		-		-		-		
Total	\$	2,562	\$	100	\$ 1,500	\$ 4,162		

Off-Balance Sheet Arrangements

It is not our usual business practice to enter into off-balance sheet arrangements such as guarantees on loans and financial commitments and retained interests in assets transferred to an unconsolidated entity for securitization purposes. We have no off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Impact of Inflation

We are subject to normal inflationary trends and anticipate that any increased costs would be passed on to our customers. Inflation has not had a material effect on our business.

Critical Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Our significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements included under Item 8 of this Part II. However, certain accounting policies are deemed "critical", as they require management's highest degree of judgment, estimates and assumptions. These accounting estimates and disclosures have been discussed with the Audit Committee of our Board of Directors. A discussion of our critical accounting policies, the judgments and uncertainties affecting their application and the likelihood that materially different amounts would be reported under different conditions or using different assumptions are as follows:

<u>Revenue Recognition – Sales Allowances</u>

When providing for the appropriate sales returns, allowances, cash discounts and cooperative incentive promotion costs ("Sales Allowances"), we apply a uniform and consistent method for making certain assumptions for estimating these provisions. These estimates and assumptions are based on historical experience, current trends and other factors that management believes to be relevant at the time the financial statements are prepared. Management reviews the accounting policies, assumptions, estimates and judgments on a quarterly basis. Actual results could differ from those estimates.

Our primary product, Cold-EEZE® cold remedy lozenges, utilizes a proprietary zinc gluconate formulation which has been clinically proven to reduce the severity and duration of common cold symptoms. Factors considered in estimating the appropriate sales returns and allowances for this product include it being (i) a unique product with limited competitors, (ii) competitively priced, (iii) promoted, (iv) unaffected for remaining shelf-life as there is no product expiration date and (v) monitored for inventory levels at major customers and third-party consumption data. In addition to Cold-EEZE® cold remedy lozenges, we market and distribute a variety of Cold-EEZE® cold remedy QuickMelts®, a Cold-EEZE® cold remedy Oral Spray, Cold-EEZE® Natural Allergy Relief caplets and Cold-EEZE® Daytime and Nighttime Multi-Symptom Relief in a liquid form. We also manufacture, market and distribute an organic cough drop and a Vitamin C supplement. Each of the Cold-EEZE® cold remedy Oral Spray and QuickMelts® products, Cold-EEZE® Natural Allergy Relief caplets, Cold-EEZE® liquid forms and organic lozenge products carry shelf-life expiration dates for which we aggregate such new product market experience data and update our sales returns and allowances estimates accordingly. Sales allowances estimates are tracked at the specific customer and product line levels and are tested on an annual historical basis, and reviewed quarterly. Additionally, we monitor current developments by customer, market conditions and any other occurrences that could affect the expected provisions relative to net sales for the period presented.

Our return policy accommodates returns for (i) discontinued products, (ii) store closings and (iii) products that have reached or exceeded their designated expiration date. We do not impose a period of time within which product may be returned. All requests for product returns must be submitted to us for pre-approval. The main components of our returns policy are: (i) we will accept returns that are due to damaged product that is un-saleable and such return request activity fall within an acceptable range, (ii) we will accept returns for products that have reached or exceeded designated expiration dates and (iii) we will accept returns in the event that we discontinue a product provided that the customer will have the right to return only such items that it purchased directly from us. We will not accept return requests pertaining to customer inventory "Overstocking" or "Resets". We will only accept return requests for product in its intended package configuration. We reserve the right to terminate shipment of product to customers who have made unauthorized deductions contrary to our return policy or pursue other methods of reimbursement. We compensate the customer for authorized returns by means of a credit applied to amounts owed or to be owed and in the case of discontinued product only, also by way of an exchange. We do not have any significant product exchange history.

We classify product returns into principally three categories, (i) non-routine returns, (ii) obsolete product and (iii) product mix realignment by certain of our customers. "Non-routine" returns are defined as product returned to us as a consequence of unanticipated circumstances principally due to (i) retail store closings or (ii) unexpected poor retail sell through to consumers causing us to discontinue the product. "Obsolete" returns are defined as product returned to us as a consequence of product shelf-life "use by" expiration date. "Product mix realignment" returns are defined as product returned to us due to initiatives by the trade to discontinue purchasing certain of our products. Product mix realignment returns are generally nominal and are frequently related to discontinued or soon to be discontinued products.

Our return policy accommodates returns for (i) discontinued products, (ii) store closings and (iii) products that have reached or exceeded designated expiration date. The following is a summary of the change in the return provision for the years ended December 31, 2015 and 2014 (in thousands):

	 Amount
Return provision at December 31, 2013	\$ 1,519
Net change in the return provision Fiscal 2014	(1)
Return provision at December 31, 2014	1,518
Net change in the return provision Fiscal 2015	 (103)
Return provision at December 31, 2015	\$ 1,415

For Fiscal 2015, 2014 and 2013, net sales of products with limited shelf-life and expiration dates were \$3.7 million, \$5.1 million and \$4.3 million, respectively.

For Fiscal 2015, the return provision decreased by \$103,000. The decrease in the return provision was principally due to (i) a charge of \$886,000, including \$514,000 for products with shelf-life expiration dates (obsolete returns), offset by (ii) net returns of \$989,000 associated principally with Fiscal 2015 and Fiscal 2014 received and processed during Fiscal 2015.

For Fiscal 2014, the return provision decreased by \$1,000. The decrease in the return provision was principally due to (i) a charge of \$1.2 million, including \$571,000 for products with shelf-life expiration dates (obsolete returns), offset by (ii) net returns of \$1.2 million associated principally with Fiscal 2014 and Fiscal 2013 received and processed during Fiscal 2014.

A one percent deviation for these sales allowance provisions for the Fiscal 2015, 2014 and 2013 would affect net sales by approximately \$248,000, \$278,000 and \$303,000, respectively. A one percent deviation for cooperative incentive promotions reserve provisions for Fiscal 2015, 2014 and 2013 could affect net sales by approximately \$224,000, \$263,000 and \$285,000, respectively.

Effect of Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, "Revenue from Contracts with Customers", on revenue recognition. The new standard provides for a single five-step model to be applied to all revenue contracts with customers as well as requires additional financial statement disclosures that will enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows relating to customer contracts. Companies have an option to use either a retrospective approach or cumulative effect adjustment approach to implement the standard. As amended by ASU No. 2015-14 issued in August 2015, this ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. We are currently assessing the impact of this update, and believe that its adoption will not have a material impact on our consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period". The amendments in this update require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Companies should apply existing guidance in ASC 718, "Compensation - Stock Compensation", as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in this update will be effective as of January 1, 2016. Earlier adoption is permitted. We may apply the amendments in this update either: (1) prospectively to all awards granted or modified after the effective date; or (2) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If a retrospective transition is adopted, the cumulative effect of applying this update as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. In addition, if a retrospective transition is adopted, we may use hindsight in measuring and recognizing the compensation cost. The adoption of ASU 2014-12 on January 1, 2016 did not have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". The amendments in this update state that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are available to be issued, when applicable). The amendments in this update are effective for the annual reporting period beginning after December 15, 2016 and for annual periods and interim periods thereafter. Early application is permitted. The adoption of ASU 2014-15 is not expected to have a material impact on our consolidated financial statements.

In February 2015, the FASB ASU No. 2015-2 "Amendments to the Consolidation Analysis" which issued guidance that changes the evaluation criteria for consolidation and related disclosure requirements. This guidance introduces evaluation criteria specific to limited partnerships and other similar entities, as well as amends the criteria for evaluating variable interest entities with which the reporting entity is involved and certain investment funds. The guidance will become effective for us at the beginning of our first quarter of Fiscal 2017. We do not expect the adoption of this guidance will have a material impact on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-3, Interest - Imputation of Interest, requiring that debt issuance costs be presented in the balance sheet as a deduction from the carrying amount of the related liability, rather than as a deferred charge. The updated guidance is effective retroactively for financial statements covering fiscal years beginning after December 15, 2015, and interim periods within those fiscal years, which for us is the first quarter of fiscal 2016. Early adoption was permitted and we elected early adoption. As of December 31, 2015, we have \$21,000 of unamortized debt issuance costs.

In July 2015, the FASB issued ASU No. 2015-11 "Simplifying the Measurement of Inventory" which requires an entity to measure inventory balances at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We are currently assessing the impact of this update, and believe that its adoption on January 1, 2017 will not have a material impact on our consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The new standard requires equity investments to be measured at fair value with changes in fair value recognized in net income, simplifies the impairment assessment of equity investments without readily determinable fair values, eliminates the requirement to disclose the methods and significant assumptions used to estimate fair value, requires use of the exit price notion when measuring fair value, requires separate presentation in certain financial statements, and requires an evaluation of the need for a valuation allowance on a deferred tax asset related to available-for-sale securities. The new standard is effective for fiscal years beginning after December 15, 2017, which for us is the first quarter of fiscal 2018. We are currently evaluating the impact this ASU will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB ASU No. 2016-02, Leases. The new standard will require most leases to be recognized on the balance sheet which will increase reported assets and liabilities. Lessor accounting remains substantially similar to current guidance. The new standard is effective for annual and interim periods in fiscal years beginning after December 15, 2018, which for us is the first quarter of fiscal 2019 and mandates a modified retrospective transition method. We are currently assessing the impact of this update, and believe that its adoption will not have a material impact on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Like virtually all commercial enterprises, we can be exposed to the risk ("market risk") that the cash flows to be received or paid relating to certain financial instruments could change as a result of changes in interest rate, exchange rates, commodity prices, equity prices and other market changes.

Our operations are not subject to risks of material foreign currency fluctuations, nor do we use derivative financial instruments in our investment practices. We place our marketable investments in instruments that meet high credit quality standards. We do not expect material losses with respect to our investment portfolio or excessive exposure to market risks associated with interest rates. The impact on our results of one percentage point change in short-term interest rates would not have a material impact on our future earnings, fair value, or cash flows related to investments in cash equivalents or interest-earning marketable securities. Our Notes bear interest at fixed rates, and therefore are not subject to market risk.

Current economic conditions may cause a decline in business and consumer spending which could adversely affect our business and financial performance including the collection of accounts receivables, realization of inventory and recoverability of assets. In addition, our business and financial performance may be adversely affected by current and future economic conditions, including a reduction in the availability of credit, financial market volatility and recession.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of ProPhase Labs, Inc.

We have audited the accompanying consolidated balance sheets of ProPhase Labs, Inc. and Subsidiaries (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2015. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ProPhase Labs, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Iselin, New Jersey March 29, 2016

PROPHASE LABS, INC AND SUBSIDARIES CONSOLIDATED BALANCE SHEETS (in thousands, except share amounts)

	December 31,				
		2015		2014	
ASSETS			_		
Cash and cash equivalents (Note 2)	\$	1,664	\$	2,926	
Accounts receivable, net (Note 2)		4,000		5,836	
Inventory (Note 2)		4,331		3,292	
Prepaid expenses and other current assets (Note 2)		1,884		1,404	
Total current assets		11,879		13,458	
Property, plant and equipment, net of accumulated depreciation of \$4,708 and \$4,341, respectively (Note 3)		2,950		2,599	
Total assets	\$	14,829	\$	16,057	
LIABILITIES AND STOCKHOLDERS' EQUITY					
LIABILITIES					
Accounts payable	\$	990	\$	667	
Accrued advertising and other allowances (Note 2)		2,508		3,685	
Other current liabilities (Notes 4 and 5)		1,036		889	
Total current liabilities		4,534		5,241	
Other long term obligation (Note 5)				100	
Secured promissory notes, net (Note 5)		1,466		100	
		1,466	_	100	
Total long term liabilities		1,400		100	
COMMITMENTS AND CONTINGENCIES (Note 9)		-		-	
STOCKHOLDERS' EQUITY					
Preferred stock, authorized 1,000,000, \$.0005 par value, no shares issued (Note 6)		-		-	
Common stock, \$.0005 par value; authorized 50,000,000; issued: 26,313,593 and					
25,125,113 shares, respectively (Note 6)		13		13	
Additional paid-in-capital		56,377		54,664	
Accumulated deficit		(16,819)		(13,219)	
Treasury stock, at cost, 9,232,817 shares (Note 6)		(30,742)		(30,742)	
Total stockholders' equity		8,829		10,716	
Total liabilities and stockholders' equity	\$	14,829	\$	16,057	

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC & SUBSIDARIES CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

		Year Ende	ed December 31,			
	2015		2014		2013	
Net sales (Notes 2 and 12)	\$ 20,604	\$	22,070	\$	25,032	
Cost of sales (Note 2)	8,426		7,891		8,361	
Gross profit	12,178		14,179		16,671	
Operating expenses:						
Sales and marketing	7,698		8,965		9,538	
Administrative	6,986		8,143		5,893	
Research and development (Note 2)	1,078		1,322		824	
Impairment charge (Note 10)	 <u>-</u>		3,577		<u>-</u>	
Total operating expense	15,762		22,007		16,255	
Income (loss) from operations	(3,584)		(7,828)		416	
Interest income	2		4		2	
Interest expense (Note 5)	(18)		(10)		(13)	
Income (loss) from operations before taxes	(3,600)		(7,834)		405	
Income tax (benefit) (Note 8)	-		-		_	
Net income (loss)	\$ (3,600)	\$	(7,834)	\$	405	
Basic income (loss) per share:						
Net income (loss)	\$ (0.22)	\$	(0.47)	\$	0.03	
Diluted income (loss) per share:						
Net income (loss)	\$ (0.22)	\$	(0.47)	\$	0.03	
Weighted average common shares outstanding:						
Basic	16,398		16,773		15,839	
Diluted	 16,398		16,773		16,276	

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC & SUBSIDARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands, except share data)

	Common Stock Shares Outstanding, Net of Shares of Treasury Stock	Additional Par Paid-In Value Capital		Retained Earnings (Deficit)	Treasury Stock	Total	
Balance at December 31, 2012	15,720,062	\$ 11	\$	42,867	\$ (5,790)	\$ (25,637)	\$ 11,451
NT-4 in a cons					405		405
Net income	25,000			27	405		405 27
Proceeds from exercise of stock options	25,000			160			
Share-based compensation expense Common stock granted pursuant to a compensation				100			160
plan	66,470			109			109
	289,474			444			444
Common stock issued (Note 6)		11	_		(F 20F)	(25 (27)	
Balance at December 31, 2013	16,101,006	11		43,607	(5,385)	(25,637)	12,596
Net loss					(7,834)		(7,834)
Share-based compensation expense				472	(7,034)		472
Common stock issued for services performed (Note				7/2			7/2
5)	300,000			393			393
Common stock granted pursuant to a compensation	500,000			373			373
plan	128,327			179			179
Common stock issued (Note 6)	3,259,727	2)	4,908			4,910
Treasury stock acquired pursuant to a settlement	-,, -			,			,
agreement (Note 6)	(3,896,764)			5,105		(5,105)	_
Balance at December 31, 2014	15,892,296	13	_	54,664	(13,219)	(30,742)	10,716
Bulance at Beechloef 31, 2011	10,072,270	13		2 1,00 1	(15,217)	(50,712)	10,710
Net loss					(3,600)		(3,600)
Issuance of warrants in connection with secure							
promissory notes (Note 5)				14			14
Share-based compensation expense				135			135
Common shares issued	1,188,480			1,564			1,564
Balance at December 31, 2015	17,080,776	\$ 13	\$	56,377	\$ (16,819)	\$ (30,742)	\$ 8,829

See accompanying notes to consolidated financial statements

PROPHASE LABS, INC & SUBSIDARIES CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

			Year En	ded December 31,		
		2015		2014		2013
Cash flows from operating activities:						
Net (loss) income	\$	(3,600)	\$	(7,834)	\$	405
Adjustments to reconcile net (loss) income to net cash						
provided by (used in) operating activities:						
Depreciation		367		277		243
Gain on the sale of fixed assets		(9)		(6)		-
Impairment charge		-		3,577		-
Share-based compensation expense		135		1,044		269
Changes in operating assets and liabilities:						
Accounts receivable		1,836		(517)		90
Inventory		(1,039)		(771)		(470)
Prepaid expenses and other assets		(480)		397		886
Accounts payable		323		(344)		(285)
Accrued advertising and other allowances		(1,177)		838		87
Other operating assets and liabilities, net		147		123		(88)
Net cash provided by (used in) operating activities		(3,497)		(3,216)		1,137
Cash flows from investing activities:						
Capital expenditures		(718)		(312)		(442)
Proceeds from the sale of fixed assets		9		6		<u>-</u>
Net cash flows used in investing activities		(709)		(306)		(442)
Cash flows from financing activities:						
Proceeds from the exercise of stock options		-		-		27
Proceeds from issuance of common stock		1,564		4,910		444
Payment of long term obligation		(100)		(100)		(100)
Secured promissory note issuance costs		(20)		-		-
Proceeds from secured promissory note		1,500		-		-
Net cash provided by financing activities		2,944		4,810		371
		(1.0(0)		1.000		1.066
Net increase (decrease) in cash and cash equivalents		(1,262)		1,288		1,066
Cash and cash equivalents at beginning of year		2,926		1,638		572
Cash and cash equivalents at beginning of year		2,720		1,030		312
Cash and cash equivalents at end of year	\$	1,664	\$	2,926	\$	1,638
			-	<u> </u>		
Supplemental disclosures of cash flow information:						
Issuance of warrants in connection with secured promissory						
notes	\$	14	\$	-	\$	-
Treasury stock acquired pursuant to a settlement agreement	\$		\$	5,105	\$	-
Interest paid	\$	6	\$	10	\$	13
Common stock issued, in lieu of cash, as payment for					_	
service	\$	-	\$	393	\$	-

See accompanying notes to consolidated financial statements

NOTE 1 – ORGANIZATION AND BUSINESS

ProPhase Labs, Inc ("we", "us" or the "Company") was initially organized as a corporation in Nevada in July 1989. Effective June 18, 2015, we changed our state of incorporation from the State of Nevada to the State of Delaware. We are a manufacturer, marketer and distributor of a diversified range of homeopathic and health care products that are offered to the general public. We are also engaged in the research and development of potential over-the-counter ("OTC") drug, natural based health products along with supplement, personal care and cosmeceutical products.

Our primary business is the manufacture, distribution, marketing and sale of OTC health care and cold remedy products to consumers through national chain, regional, specialty and local retail stores. Our flagship brand is Cold-EEZE and our principal product is Cold-EEZE cold remedy zinc gluconate lozenges, proven in clinical studies to reduce the duration and severity of symptoms of the common cold. In addition to Cold-EEZE cold remedy lozenges, we market and distribute non-lozenge forms of our proprietary zinc gluconate formulation, (i) Cold-EEZE cold remedy QuickMelts and (ii) Cold-EEZE cold remedy Oral Spray. Each of these new Cold-EEZE QuickMelts products are based on our proprietary zinc gluconate formulation in combination with certain natural (i) immune system support, (ii) energy, (iii) sleep and relaxation, and/or (iv) cold and flu symptom relieving active ingredients. In Fiscal 2015, we introduced three new Cold-EEZE product line extensions: (i) a Cold-EEZE Multi-Symptom Relief for Cold and Flu lozenge, (ii) a Cold-EEZE Daytime and Nighttime Multi-Symptom Relief in liquid form for each of adults and children, and (iii) Cold-EEZE Natural Allergy Relief caplets for indoor and outdoor allergies. Shipments for these three new Cold-EEZE product line extensions began in the third quarter of Fiscal 2015. We also manufacture, market and distribute organic cough drops and a Vitamin C supplement, and perform contract manufacturing services of cough drop and other OTC cold remedy products for third parties.

Cold-EEZE[®] is an established product in the health care and cold remedy market. For Fiscal 2015, 2014 and 2013, our revenues have come principally from our OTC health care and cold remedy products. For Fiscal 2015, 2014 and 2013, our net sales for each period were related to markets in the United States.

Our business is subject to seasonal variations thereby impacting liquidity and working capital during the course of our fiscal year.

We use a December 31 year-end for financial reporting purposes. References herein to the fiscal year ended December 31, 2015 shall be the term "Fiscal 2015" and references to other "Fiscal" years shall mean the year, which ended on December 31 of the year indicated. The term the "we", "us: or the "Company" as used herein also refer, where appropriate, to the Company, together with its subsidiaries unless the context otherwise requires.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements ("Financial Statements") include the accounts of the Company and its wholly owned subsidiaries and Phusion Laboratories LLC ("Phusion"), a variable interest entity (see Note 10). All intercompany transactions and balances have been eliminated.

Seasonality of the Business

Our net sales are derived principally from our OTC health care and cold remedy products. Currently, our sales are influenced by and subject to fluctuations in the timing of purchase and the ultimate level of demand for our products which are a function of the timing, length and severity of each cold season. Generally, a cold season is defined as the period of September to March when the incidence of the common cold and flu rises as a consequence of the change in weather and other factors. We generally experience in the third and fourth quarter higher levels of net sales along with a corresponding increase in marketing and advertising expenditures designed to promote its products during the cold season. Revenues and related marketing costs are generally at their lowest levels in the second quarter when consumer demand generally declines. We track health and wellness trends and develop retail promotional strategies to align our production scheduling, inventory management and marketing programs to optimize consumer purchases.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

As a consequence of the seasonally of our business, we realize variations in operating results and demand for working capital from quarter to quarter. As of December 31, 2015, we had working capital of approximately \$7.3 million and we have 2,450,000 shares of our common stock, \$.0005 par value ("Common Stock") available for sale under our 2015 equity line of credit (see Note 6). Additionally, on December 11, 2015, we executed two Subscription Agreements (the "Subscription Agreements") with the investors named therein (the "Investors") providing for the purchase of 12% Secured Promissory Notes – Series A ("Notes") in the aggregate principal amount of up to \$3.0 million and warrants to purchase shares of our Common Stock (the "Warrants"). We issued Notes in the amount of \$1,500,000 and 51,000 Warrants, at an exercise price of \$1.35 per share (see Note 5). We believe our current working capital and available equity line of credit and an available \$1.5 million in additional debt financing through the Subscription Agreements is an acceptable and adequate level of working capital to support our business for at least the next twelve months ending March 31, 2017.

Use of Estimates

The preparation of financial statements and the accompanying notes thereto, in conformity with generally accepted accounting principles in the United States of America ("GAAP"), requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the respective reporting periods. Examples include the provision for bad debt, sales returns and allowances, inventory obsolescence, useful lives of property and equipment and intangible assets, impairment of property and equipment and intangible assets, income tax valuations and assumptions related to accrued advertising. When providing for the appropriate sales returns, allowances, cash discounts and cooperative incentive promotion costs ("Sales Allowances"), we apply a uniform and consistent method for making certain assumptions for estimating these provisions. These estimates and assumptions are based on historical experience, current trends and other factors that management believes to be relevant at the time the financial statements are prepared. Management reviews the accounting policies, assumptions, estimates and judgments on a quarterly basis. Actual results could differ from those estimates.

Our primary product, Cold-EEZE® cold remedy lozenges, utilizes a proprietary zinc gluconate formulation which has been clinically proven to reduce the severity and duration of common cold symptoms. Factors considered in estimating the appropriate sales returns and allowances for this product include it being (i) a unique product with limited competitors, (ii) competitively priced, (iii) promoted, (iv) unaffected for remaining shelf-life as there is no product expiration date and (v) monitored for inventory levels at major customers and third-party consumption data. In addition to Cold-EEZE® cold remedy lozenges, we market and distribute a variety of Cold-EEZE® cold remedy QuickMelts®, a Cold-EEZE® cold remedy Oral Spray, Cold-EEZE® Natural Allergy Relief caplets and Cold-EEZE® Daytime and Nighttime Multi-Symptom Relief in a liquid form. We also manufacture, market and distribute an organic cough drop and a Vitamin C supplement. Each of the Cold-EEZE® cold remedy Oral Spray and QuickMelts® products, Cold-EEZE® Natural Allergy Relief caplets, Cold-EEZE® liquid forms and organic lozenge products carry shelf-life expiration dates for which we aggregate such new product market experience data and update our sales returns and allowances estimates accordingly. Sales allowances estimates are tracked at the specific customer and product line levels and are tested on an annual historical basis, and reviewed quarterly. Additionally, we monitor current developments by customer, market conditions and any other occurrences that could affect the expected provisions relative to net sales for the period presented.

Cash Equivalents

We consider all highly liquid investments with an initial maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents include cash on hand and monies invested in money market funds. The carrying amount approximates the fair market value due to the short-term maturity of these investments.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

Inventory

Inventory is valued at the lower of cost, determined on a first-in, first-out basis (FIFO), or market. Inventory items are analyzed to determine cost and the market value and appropriate valuation adjustments are established. At December 31, 2015 and 2014, the financial statements include adjustments to reduce inventory for excess or obsolete inventory of \$501,000 and \$797,000, respectively. The components of inventory are as follows (in thousands):

		December 31,							
		2015		2014					
Raw materials	\$	1,303	\$	798					
Work in process	Ψ	530	Ψ	418					
Finished goods		2,498		2,076					
	\$	4,331	\$	3,292					

Property, Plant and Equipment

Property, plant and equipment are recorded at cost. We use the straight-line method in computing depreciation for financial reporting purposes. The depreciation expense is computed in accordance with the estimated asset lives (see Note 3).

Concentration of Risks

Future revenues, costs, margins and profits will continue to be influenced by our ability to maintain our manufacturing availability and capacity together with our marketing and distribution capabilities and the requirements associated with the development of OTC and other personal care products in order to continue to compete on a national and/or international level.

Our business is subject to federal and state laws and regulations adopted for the health and safety of users of our products. Our OTC cold remedy products are subject to regulations by various federal, state and local agencies, including the Food and Drug Administration ("FDA") and, as applicable, the Homeopathic Pharmacopoeia of the United States.

Financial instruments that potentially subject us to significant concentrations of credit risk consist principally of cash investments and trade accounts receivable.

We maintain cash and cash equivalents with certain major financial institutions. As of December 31, 2015, our cash and cash equivalents were \$1.7 million and our bank balance was \$2.2 million. Of the total bank balance, \$660,000 was covered by federal depository insurance and \$1.6 million was uninsured.

Trade accounts receivable potentially subjects us to credit risk. We extend credit to our customers based upon an evaluation of the customer's financial condition and credit history and generally we do not require collateral. Our broad range of customers includes many national chain, regional, specialty and local retail stores (see Note 12). During Fiscal 2015, 2014 and 2013, effectively all of our net revenues were related to domestic markets.

Our revenues are principally generated from the sale of OTC health care and cold remedy products which approximated 90%, 94% and 94% of total revenues for Fiscal 2015, 2014 and 2013, respectively. A significant portion of our business is highly seasonal, which causes major variations in operating results from quarter to quarter. The first and fourth quarters generally represent the largest sales volume for the OTC health care and cold remedy products.

Raw materials used in the production of the products are available from numerous sources. Certain raw material active ingredients used in connection with Cold-EEZE® products are purchased from a single unaffiliated supplier. Should the relationship terminate or the vendor become unable to supply material, we believe that the current contingency plans would prevent a termination from materially affecting our operations. However, if the relationship was terminated, there may be delays in production of our products until an acceptable replacement supplier is located.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

Long-lived Assets

We review the carrying value of our long-lived assets with definite lives whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. When indicators of impairment exist, we determine whether the estimated undiscounted sum of the future cash flows of such assets is less than their carrying amounts. If less, an impairment loss is recognized in the amount, if any, by which the carrying amount of such assets exceeds their respective fair values. The determination of fair value is based on quoted market prices in active markets, if available, or independent appraisals; sales price negotiations; or projected future cash flows discounted at a rate determined by management to be commensurate with our business risk. The estimation of fair value utilizing discounted forecasted cash flows includes significant judgments regarding assumptions of revenue, operating and marketing costs; selling and administrative expenses; interest rates; property and equipment additions and retirements; industry competition; and general economic and business conditions, among other factors.

Fair value is based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a three-tier fair value hierarchy prioritizes the inputs used to measure fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Revenue Recognition

Sales are recognized at the time ownership is transferred to the customer. Revenue is reduced for trade promotions, estimated sales returns, cash discounts and other allowances in the same period as the related sales are recorded. We make estimates of potential future product returns and other allowances related to current period revenue. We analyze historical returns, current trends, and changes in customer and consumer demand when evaluating the adequacy of the sales returns and other allowances.

Our return policy accommodates returns for (i) discontinued products, (ii) store closings and (iii) products that have reached or exceeded their designated expiration date. We do not impose a period of time within which product may be returned. All requests for product returns must be submitted to us for pre-approval. The main components of our returns policy are: (i) we will accept returns that are due to damaged product that is un-saleable and such return request activity fall within an acceptable range, (ii) we will accept returns for products that have reached or exceeded designated expiration dates and (iii) we will accept returns in the event that we discontinue a product provided that the customer will have the right to return only such items that it purchased directly from us. We will not accept return requests pertaining to customer inventory "Overstocking" or "Resets". We will only accept return requests for product in its intended package configuration. We reserve the right to terminate shipment of product to customers who have made unauthorized deductions contrary to our return policy or pursue other methods of reimbursement. We compensate the customer for authorized returns by means of a credit applied to amounts owed or to be owed and in the case of discontinued product only, also by way of an exchange. We do not have any significant product exchange history.

As of December 31, 2015 and 2014, we included a provision for sales allowances of \$83,000 and \$129,000, respectively, which are reported as a reduction to account receivables. Additionally, accrued advertising and other allowances as of December 31, 2015 include \$1.4 million for estimated future sales returns and \$786,000 for cooperative incentive promotion costs. As of December 31, 2014, accrued advertising and other allowances include \$1.5 million for estimated future sales returns and \$2.1 million for cooperative incentive promotion costs.

Shipping and Handling

Product sales carry shipping and handling charges to the purchaser, included as part of the invoiced price, which is classified as revenue. In all cases, costs related to this revenue are recorded in cost of sales.

Stock Compensation

We recognize all share-based payments to employees and directors, including grants of stock options, as compensation expense in the financial statements based on their fair values. Fair values of stock options are determined through the use of the Black-Scholes option pricing model. The compensation cost is recognized as an expense over the requisite service period of the award, which usually coincides with the vesting period.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

Stock and stock options for purchase of our Common Stock have been granted to both employees and non-employees pursuant to the terms of certain agreements and stock option plans (see Note 6). Stock options are exercisable during a period determined by us, but in no event later than ten years from the date granted. In Fiscal 2015, 2014 and 2013, we charged to operations \$135,000, \$1.0 million and \$269,000, respectively, for share-based compensation expense for the aggregate fair value of stock and stock grants issued, and vested stock options earned.

Variable Interest Entity

The Joint Venture, of which we own a 50% membership interest, qualifies as a variable interest entity ("VIE") and we have consolidated the Phusion joint venture (see Note 10).

Advertising and Incentive Promotions

Advertising and incentive promotion costs are expensed within the period in which they are utilized. Advertising and incentive promotion expense is comprised of media advertising, presented as part of sales and marketing expense; cooperative incentive promotions and coupon program expenses, which are accounted for as part of net sales; and free product, which is accounted for as part of cost of sales. Advertising and incentive promotion costs incurred for Fiscal 2015, 2014 and 2013 were \$8.5 million, \$10.9 million and \$10.8 million, respectively. At December 31, 2015 and 2014, prepaid expenses and other current assets included \$854,000 and \$885,000, respectively, relating to prepaid deposits for advertising and promotion programs scheduled principally for the first quarter of Fiscal 2016 and 2015, respectively.

Research and Development

Research and development costs are charged to operations in the period incurred. Expenditures for Fiscal 2015, 2014 and 2013 were \$1.1 million, \$1.3 million, and \$824,000, respectively. For Fiscal 2015, Fiscal 2014 and Fiscal 2013, research and development costs are related principally to new product development initiatives and costs associated with OTC health care and cold remedy products.

Income Taxes

We utilize the asset and liability approach which requires the recognition of deferred tax assets and liabilities for the future tax consequences of events that have been recognized in our financial statements or tax returns. In estimating future tax consequences, we generally consider all expected future events other than enactments of changes in the tax law or rates. Until sufficient taxable income to offset the temporary timing differences attributable to operations and the tax deductions attributable to option, warrant and stock activities are assured, a valuation allowance equaling the total net current and non-current deferred tax asset is being provided (see Note 8).

We utilize a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than fifty percent likely of being realized upon ultimate settlement. Any interest or penalties related to uncertain tax positions will be recorded as interest or administrative expense, respectively.

The major jurisdiction for which we file income tax returns is the United States.

Fair Value of Financial Instruments

Cash and cash equivalents, accounts receivable, accounts payable, accrued expense and notes payable are reflected in the Financial Statements at carrying value which approximates fair value.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, "Revenue from Contracts with Customers", on revenue recognition. The new standard provides for a single five-step model to be applied to all revenue contracts with customers as well as requires additional financial statement disclosures that will enable users to understand the nature, amount, timing and uncertainty of revenue and cash flows relating to customer contracts. Companies have an option to use either a retrospective approach or cumulative effect adjustment approach to implement the standard. As amended by ASU No. 2015-14 issued in August 2015, this ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. We are currently assessing the impact of this update, and believe that its adoption will not have a material impact on our consolidated financial statements

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period". The amendments in this update require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Companies should apply existing guidance in ASC 718, "Compensation - Stock Compensation", as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in this update will be effective as of January 1, 2016. Earlier adoption is permitted. We may apply the amendments in this update either: (1) prospectively to all awards granted or modified after the effective date; or (2) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If a retrospective transition is adopted, the cumulative effect of applying this update as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. In addition, if a retrospective transition is adopted, we may use hindsight in measuring and recognizing the compensation cost. The adoption of ASU 2014-12 on January 1, 2016 did not have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". The amendments in this update state that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are available to be issued, when applicable). The amendments in this update are effective for the annual reporting period beginning after December 15, 2016 and for annual periods and interim periods thereafter. Early application is permitted. The adoption of ASU 2014-15 is not expected to have a material impact on our consolidated financial statements.

In February 2015, the FASB ASU No. 2015-2 "Amendments to the Consolidation Analysis" which issued guidance that changes the evaluation criteria for consolidation and related disclosure requirements. This guidance introduces evaluation criteria specific to limited partnerships and other similar entities, as well as amends the criteria for evaluating variable interest entities with which the reporting entity is involved and certain investment funds. The guidance will become effective for us at the beginning of our first quarter of Fiscal 2017. We do not expect the adoption of this guidance will have a material impact on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-3, Interest - Imputation of Interest, requiring that debt issuance costs be presented in the balance sheet as a deduction from the carrying amount of the related liability, rather than as a deferred charge. The updated guidance is effective retroactively for financial statements covering fiscal years beginning after December 15, 2015, and interim periods within those fiscal years, which for us is the first quarter of fiscal 2016. Early adoption was permitted and we elected early adoption. As of December 31, 2015, we have \$21,000 of unamortized debt issuance costs.

In July 2015, the FASB issued ASU No. 2015-11 "Simplifying the Measurement of Inventory" which requires an entity to measure inventory balances at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We are currently assessing the impact of this update, and believe that its adoption on January 1, 2017 will not have a material impact on our consolidated financial statements.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - (continued)

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The new standard requires equity investments to be measured at fair value with changes in fair value recognized in net income, simplifies the impairment assessment of equity investments without readily determinable fair values, eliminates the requirement to disclose the methods and significant assumptions used to estimate fair value, requires use of the exit price notion when measuring fair value, requires separate presentation in certain financial statements, and requires an evaluation of the need for a valuation allowance on a deferred tax asset related to available-for-sale securities. The new standard is effective for fiscal years beginning after December 15, 2017, which for us is the first quarter of fiscal 2018. We are currently evaluating the impact this ASU will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB ASU No. 2016-02, Leases. The new standard will require most leases to be recognized on the balance sheet which will increase reported assets and liabilities. Lessor accounting remains substantially similar to current guidance. The new standard is effective for annual and interim periods in fiscal years beginning after December 15, 2018, which for us is the first quarter of fiscal 2019 and mandates a modified retrospective transition method. We are currently assessing the impact of this update, and believe that its adoption will not have a material impact on our consolidated financial statements.

NOTE 3 - PROPERTY, PLANT AND EQUIPMENT

The components of property and equipment are as follows (in thousands):

		Decem			
		2015		2014	Estimated Useful Life
	Ф	504	Φ.	504	
Land	\$	504	\$	504	
Buildings and improvements		3,016		3,016	10 - 39 years
Machinery and equipment		3,623		2,933	3 - 7 years
Computer equipment and software		319		291	3 - 5 years
Furniture and fixtures		196		196	5 years
		7,658		6,940	•
Less: Accumulated depreciation		4,708		4,341	
	\$	2,950	\$	2,599	

Depreciation expense for Fiscal 2015, 2014 and 2013 was \$367,000, \$277,000 and \$243,000, respectively.

NOTE 4 – OTHER CURRENT LIABILITIES

At December 31, 2015 and 2014, other current liabilities include \$484,000 and \$372,000, respectively, related to accrued compensation and \$100,000 and \$200,000, respectively, related to the Godfrey Settlement Agreement (see Note 5).

NOTE 5 – SECURED PROMISSORY NOTES AND OTHER OBLIGATIONS

Secured Promissory Notes

On December 11, 2015, we executed two Subscription Agreements with Investors providing for the purchase of the Notes in the aggregate principal amount of up to \$3.0 million and Warrants. The Warrants grant the Investors the right to purchase 17,000 shares of common stock for every \$500,000 of principal amount of Notes purchased by the Investors.

NOTE 5 - SECURED PROMISSORY NOTES AND OTHER OBLIGATIONS - (continued)

Notes in the amount of \$1,500,000 and 51,000 Warrants, at an exercise price of \$1.35 per share, which is equal to the closing price of our Common Stock on the date of investment, were issued by the Company and its wholly-owned subsidiaries Pharmaloz Manufacturing Inc. and Quigley Pharma Inc. (collectively, the "Obligors") and funded on December 11, 2015. We incurred loan origination costs of \$22,000 which was recorded as a reduction of the Notes and the origination costs are charged to interest expense over the term of the loan. The Warrants have an exercise term equal to three years and are exercisable commencing on the date of issuance. The fair value of the Warrants at the date of grant was \$14,000 which is recorded as a reduction of the Notes and is charged to interest expense over the term of the loan (see Note 6). At December 31, 2015, the \$1.5 million Notes are reported net of \$34,000 of the unamortized interest for the loan origination costs and unamortized interest for the Warrants. At December 31, 2015, other current liabilities include \$10,000 for accrued interest under the terms of the Notes.

The Notes are secured by all of our tangible and intangible assets. The Notes bear interest at the rate of 12% per annum, payable semi-annually and the principal is due and payable on June 15, 2017. The Notes may be pre-paid at any time prior to maturity without penalty. The effective interest, inclusive of the Warrant and loan origination costs, is 14.3% per annum. We charged to interest expense \$11,000 for the period December 11, 2015 to December 31, 2015 in connection with the Notes.

The offers and sales of the Notes and Warrants were made without registration under the Securities Act, or the securities laws of certain states, in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act and Regulation D under the Securities Act and in reliance on similar exemptions under applicable state laws.

In connection with the issuance of the Notes, we entered into a security agreement with John E. Ligums, Jr. (an Investor and a shareholder in the Company), as collateral agent for the Investors (the "Security Agreement") to secure the timely payment and performance in full of the Obligors' obligations pursuant to the Notes. Under the Security Agreement, the Obligors grant to the Collateral Agent, for the benefit of the Investors a lien upon and security interest in the property and assets listed as collateral in the Security Agreement, including without limitation, all of the Obligors' personal property, inventory, equipment, general intangibles, cash and cash equivalents, and proceeds.

Godfrey Settlement Agreement

In November 2004 we commenced an action against John C. Godfrey, Nancy Jane Godfrey, and Godfrey Science and Design, Inc. (together the "Godfreys") for injunctive relief regarding the ownership of the Cold-EEZE® trademark. The Godfreys subsequently asserted against us counterclaims and sought monetary damages and injunctive and declaratory relief relative to the Cold-EEZE® trademark and other intellectual property.

On December 20, 2012, we and the Godfreys, including the Estate of Nancy Jane Godfrey, entered into a Settlement Agreement and Mutual General Release (the "Godfrey Settlement Agreement"), pursuant to which we resolved all disputes, including claims asserted by us and counterclaims asserted against us in the action. Pursuant to the terms of the Godfrey Settlement Agreement, we paid the Godfreys \$2.1 million in December 2012 and we agreed to make four additional annual payments of \$100,000 due in December of each of the next four years. Each annual payment in the amount of \$100,000 accrues interest at the per annum rate of 3.25%. The annual installment of \$107,000, \$110,000 and \$113,000, inclusive of accrued interest, were paid in December 2015, 2014 and 2013, respectively. Under the Godfrey Settlement Agreement, the Godfreys assigned, transferred and conveyed to us all of their right, title, and interest in U.S. Trademark Registration No. 1,838,542 for the trademark Cold-EEZE®, among other intellectual property associated with such trademark. At December 31, 2015, other current liabilities include \$100,000, for the remaining annual installment payment due in Fiscal 2016.

The future obligations of our Notes and Settlement Agreement over the next five years are as follows:

Year	Settl	dfrey ement ement		Notes	 Total
2016	\$	100	\$	-	\$ 100
2017		-		1,500	1,500
2018		-		-	-
2019		-		-	-
2020		-		-	-
Total	\$	100	\$	1,500	\$ 1,600
		_	43 -		

NOTE 6 - STOCKHOLDERS' EQUITY AND STOCK COMPENSATION

Our authorized capital stock consists of 50 million shares of Common Stock and 1 million shares of preferred stock, \$.0005 par value ("Preferred Stock").

Preferred Stock

On June 16, 2015, our shareholders approved the change our state of incorporation from the State of Nevada to the State of Delaware pursuant to a plan of conversion ("Conversion Plan") and the filing of a certificate of incorporation in the State of Delaware. The Preferred Stock authorized under our certificate of incorporation may be issued from time to time in one or more series. As of December 31, 2015, no shares of Preferred Stock have been issued. Our board of directors has the full authority permitted by law to establish, without further stockholder approval, one or more series and the number of shares constituting each such series and to fix by resolution voting powers, preferences and relative, participating, optional and other special rights of each series of Preferred Stock, and the qualifications, limitations or restrictions thereof, if any. Subject to the limitation on the total number of shares of Preferred Stock that we have authority to issue under our certificate of incorporation, the board of directors is also authorized to increase or decrease the number of shares of any series, subsequent to the issue of that series, but not below the number of shares of such series then-outstanding. In case the number of shares of any series is so decreased, the shares constituting such decrease will resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. We may amend from time to time our certificate of incorporation and bylaws to increase the number of authorized shares of Preferred Stock or Common Stock or to make other changes or additions.

Stockholder Rights Plan

On September 8, 1998, our Board of Directors declared a dividend distribution of Common Stock Purchase Rights (each individually, a "Right" and collectively, the "Rights") payable to the stockholders of record on September 25, 1998, thereby creating a Stockholder Rights Plan (the "Rights Agreement"). The Rights Agreement was subsequently amended effective each of (i) May 23, 2008, (ii) August 18, 2009 and (iii) June 2014. The Rights Agreement, as amended and restated, provides that each Right entitles the stockholder of record to purchase from the Company that number of common shares of Common Stock having a combined market value equal to two times the Rights exercise price of \$45. The Rights are not exercisable until the distribution date, which will be the earlier of a public announcement that a person or group of affiliated or associated persons has acquired 15% or more of the outstanding common shares of Common Stock, or the announcement of an intention by a similarly constituted party to make a tender or exchange offer resulting in the ownership of 15% or more of the outstanding common shares of Common Stock (such person, the "acquirer"). The Rights Agreement, as amended and restated, allows for an exemption for Ted Karkus, our Chairman and Chief Executive Officer, to acquire up to 20% of our Common Stock without our Board of Directors declaring a dividend distribution.

The dividend has the effect of giving the stockholder a 50% discount on the share's current market value for exercising such right. In the event of a cashless exercise of the Right, and the acquirer has acquired less than 50% beneficial ownership of the Company, a stockholder may exchange one Right for one common share of the Company. The Rights Agreement, as amended and restated, includes a provision pursuant to which our Board of Directors may exempt from the provisions of the Rights Agreement an offer for all outstanding shares of our Common Stock that the directors determine to be fair and not inadequate and to otherwise be in the best interests of the Company and its stockholders, after receiving advice from one or more investment banking firms. The expiration date of the Rights Agreement, as amended and retstated, is June 18, 2024.

2012 Equity Line of Credit

On November 21, 2012, we entered into the equity line of credit agreement (such arrangement, the "2012 Equity Line") with Dutchess Opportunity Fund II, LP ("Dutchess") whereby Dutchess committed to purchase, subject to certain restrictions and conditions, up to 2,500,000 shares of our Common Stock, over a period of 36 months from the first trading day following the effectiveness of the registration statement registering the resale of shares purchased by Dutchess pursuant to the 2012 Equity Line. On November 26, 2012, we filed a registration statement with the SEC to register for sale for up to 2,500,000 shares of our Common Stock and the registration statement was deemed effective by the SEC on December 12, 2012. We amended this registration statement effective May 29, 2014 to withdraw and remove from registration all unissued and unsold shares. We also agreed with Dutchess to terminate the 2012 Equity Line as of May 28, 2014.

During Fiscal 2013, we sold an aggregate of 289,474 shares of Common Stock to Dutchess under the and pursuant to the 2012 Equity Line and we derived net proceeds of \$445,000. During the period January 1, 2014 through May 23, 2014, we sold an aggregate of 698,207 shares of Common Stock to Dutchess under and pursuant to the 2012 Equity Line and we derived net proceeds of \$1.2 million. The sales of the shares under the 2012 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended in reliance upon Section 4(2) (or Regulation D promulgated thereunder).

NOTE 6 - STOCKHOLDERS' EQUITY AND STOCK COMPENSATION - (continued)

2014 Equity Line of Credit

On May 28, 2014, we entered into a equity line of credit agreement (such arrangement, the "2014 Equity Line") with Dutchess whereby Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,000,000 shares of our Common Stock, over a period of 36 months from the effectiveness of the registration statement registering the resale of shares purchased by Dutchess pursuant to the Investment Agreement. On May 29, 2014, we filed a registration statement with the SEC to register for sale up to 3,000,000 shares of our Common Stock and the registration statement was declared effective by the SEC on June 4, 2014.

During the period June 4, 2014 through September 30, 2014, we sold an aggregate of 2,561,520 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of \$3.7 million. In June 2015, we sold an aggregate of 438,480 shares of our Common Stock to Dutchess under and pursuant to the 2014 Equity Line and we derived net proceeds of \$524,000. The sales of the shares under the 2014 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended in reliance upon Section 4(a)(2) (or Regulation D promulgated thereunder). At June 30, 2015, there were no shares of our Common Stock available for sale under the terms of the 2014 Equity Line. As a consequence of the utilization of the 2014 Equity Line, on July 23, 2015 we filed a post-effective amendment to the underlying registration statement for the 2014 Equity Line to terminate the registration statement.

2015 Equity Line of Credit

On July 30, 2015, we entered into a new equity line of credit agreement (such arrangement, the "2015 Equity Line") with Dutchess. Pursuant to the 2015 Equity Line, Dutchess committed to purchase, subject to certain restrictions and conditions, up to 3,200,000 shares of our Common Stock, over a period of 36 months from the effectiveness of the registration statement registering the resale of shares purchased by Dutchess pursuant to the Investment Agreement.

We may, at our discretion, draw on the 2015 Equity Line from time to time, as and when we determine appropriate in accordance with the terms and conditions of the 2015 Equity Line. The maximum number of shares that we are entitled to put to Dutchess in any one draw down notice shall not exceed 500,000 shares with a purchase price calculated in accordance with the 2015 Equity Line. We may deliver a notice for a subsequent put from time to time, following the one day pricing period for the prior put.

The purchase price shall be set at ninety-five percent (95%) of the volume weighted average price (VWAP) of the Common Stock during the one trading day immediately following our put notice. We have the right to withdraw all or any portion of any put, except that portion of the put that has already been sold to a third party, including any portion of a put that is below the minimum acceptable price set forth on the put notice, before the closing. In the event Dutchess receives more than a five percent (5%) return on the net sales for a specific put, Dutchess must remit such excess proceeds to us; however, in the event Dutchess receives less than a five percent (5%) return on the net sales for a specific put, Dutchess will have the right to deduct from the proceeds of the put amount on the applicable closing date so Dutchess's return will equal five percent (5%).

There are put restrictions applied on days between the draw down notice date and the closing date with respect to that particular put. During such time, we are entitled to deliver another draw down notice. In addition, Dutchess will not be obligated to purchase shares if Dutchess' total number of shares beneficially held at that time would exceed 4.99% of the number of shares of Common Stock as determined in accordance with Rule 13d-1(j) of the Securities Exchange Act of 1934, as amended. In addition, we are not permitted to draw on the facility unless there is an effective registration statement to cover the resale of the shares.

Pursuant to the terms of the 2015 Equity Line, we are obligated to file one or more registrations statements with the SEC to register the resale by Dutchess of the shares of Common Stock issued or issuable under the 2015 Equity Line. In addition, we are obligated to use all commercially reasonable efforts to have the registration statement declared effective by the SEC within 90 days after the registration statement is filed. On August 4, 2015, we filed a registration statement for the underlying shares of the 2015 Equity Line with the SEC and the registration statement was declared effective by the SEC on August 21, 2015.

NOTE 6 - STOCKHOLDERS' EQUITY AND STOCK COMPENSATION - (continued)

During the period August 21, 2015 through December 31, 2015, we sold an aggregate of 750,000 shares of our Common Stock to Dutchess under and pursuant to the 2015 Equity Line and we derived net proceeds of \$1.0 million. The sales of the shares under the 2015 Equity Line were deemed to be exempt from registration under the Securities Act of 1933, as amended in reliance upon Section 4(2) (or Regulation D promulgated thereunder). At December 31, 2015 we have 2,450,000 shares of our Common Stock available for sale, at our discretion, under the terms of the 2015 Equity Line and covered pursuant to a registration statement.

The 2010 Equity Compensation Plan

On May 5, 2010, our shareholders approved the 2010 Equity Compensation Plan which was subsequently amended, restated and approved by our shareholders on April 24, 2011 and further amended and approved by shareholders on May 6, 2013 (the "2010 Plan"). The 2010 Plan provides that the total number of shares of Common Stock that may be issued under the 2010 Plan is equal to 2.5 million shares, including 900,000 shares that are authorized for issuance but unissued under the 1997 incentive stock option ("1997 Plan"). At December 31, 2014, there are 1,713,000 options outstanding under the 2010 Equity Compensation Plan (see "Stock Options" below).

Stock Options and Warrants Fair Value

All of our employees, including employees who are officers or members of the Board are eligible to participate in the 2010 Plan. Consultants and advisors who perform services for us are also eligible to participate in the 2010 Plan. For Fiscal 2015, there were no options granted under the 2010 Plan. Pursuant to the terms of the Subscriptions Agreements for the Notes (see Note 5), we issued 51,000 Warrants in December 2015. For Fiscal 2014 and 2013, we granted, 147,500 and 420,500 options, respectively, to employees to acquire our Common Stock pursuant to the terms of 2010 Plan. Presented below is a summary of the terms of the grant of options and warrants:

	Year Ended December 31,					
	2015		2014		2013	
Number of options granted	 -		147,500		420,500	
Number of Warrants granted	51,000		-		-	
Vesting period	none		none		2 - 3 years	
Maximum term of option or Warrants from date of						
grant	3 years		7 years		6 - 7 years	
Exercise price per share	\$ 1.35	\$	1.39		\$1.48 - \$1.65	
Weighted average fair value per share of options and Warrants granted during the year	\$ 0.26	\$	0.59	\$	0.56	

We used the Black-Scholes option pricing model during Fiscal 2015, 2014 and 2013 to determine the fair value of the stock options and warrants at the date of grant. Based upon our limited historical experience, we determined the expected term of the stock option grants to be a range between 2.5 to 6.5 years, calculated using the "simplified" method in accordance with the SEC Staff Accounting Bulletin 110. We use the "simplified" method since our historical data does not provide a reasonable basis upon which to estimate expected term.

Presented below is a summary of assumptions used in determining the fair value of the stock options and Warrants at the date of grant:

	Year I	Year Ended December 31,						
	2015	2014	2013					
Expected option or Warrant life	3 years	3.5 years	3.75 - 4.5 years					
Weighted average risk free rate	0.88%	0.10%	0.36%					
Dividend yield	0%	0%	0%					
Expected volatility	26.42%	52.43%	47.33% - 82.09%					
	16							

NOTE 6 - STOCKHOLDERS' EQUITY AND STOCK COMPENSATION - (continued)

The fair value of the stock options and Warrants at the time of the grant in Fiscal 2015, 2014 and 2013 was \$14,000, \$87,000 and \$237,000, respectively. For Fiscal 2015 and 2014 stock options and Warrants granted were not subject to a vesting period. Additionally, the remaining vesting period for options originally issued in Fiscal 2010 of 200,000 was accelerated to be fully vested at December 31, 2014. The aggregate fair value of \$217,000 for each of the stock options granted in Fiscal 2014 and the accelerated vesting period of previously issued options of \$255,000 were charged to operations in Fiscal 2014. The stock options granted for Fiscal 2013 were subject to vesting such that the fair value of the stock options granted is charged to operations over the vesting period. For Fiscal 2015, 2014 and 2013, we charged to operations \$135,000, \$472,000 and \$160,000, respectively, for share-based compensation expense for the aggregate fair value of the vested stock options earned

Stock Options

At December 31, 2014, of the options granted under the 2010 Equity Compensation Plan 1,709,250 were vested and 3,750 are subject to vesting. At December 31, 2015, there are 19,659 options available for grant to purchase shares of Common Stock that may be issued pursuant to the terms of the 2010 Plan.

A summary of the status of our stock options granted pursuant the 1997 Plan and the 2010 Plan as of December 31, 2015, 2014 and 2013 and changes during the years then ended is presented below (in thousands, except per share data):

	Year Ended December 31,									
	2	,	2	2014				2013		
	Weighted					Weighted		Weighted		
			Average			Average			Average	
			Exercise			Exercise		F	Exercise	
	Shares		Price	Shares		Price	Shares		Price	
Options outstanding - beginning of year	1,740	\$	1.40	1,638	\$	1.60	1,307	\$	1.72	
Granted	-		-	148		1.39	420		1.64	
Exercised	-		-	-		-	(25)		1.08	
Cancelled	(27)		13.50	(46)		9.50	(64)		4.53	
Options outstanding - end of year	1,713	\$	1.21	1,740	\$	1.40	1,638	\$	1.60	
Options granted and subject to future vesting	4	\$	1.48	263	\$	1.54	884	\$	1.32	
Exercisable, at end of year	1,709			1,477			1,085			
Available for grant	20			20			262			

The unrecognized share-based compensation expense related to the options granted but not vested, (options to acquire 3,750 shares) was \$2,000 at December 31, 2015. These options subject to vesting (i) vest over the next year, (ii) have a 7 year term from the date of grant, (iii) are exercisable at a weighted average price of \$1.48 and (iv) the unrecognized share-based compensation expense is expected to be recognized over a weighted average period of 4 months.

The following table summarizes information about stock options outstanding and stock options exercisable at December 31, 2015 (in thousands, except remaining life and per share data):

	Options Outstanding and Exercisable								
	Weighted Average								
Range of	Number	Remaining	W	eighted Average					
Exercise Prices	Outstanding	Contractual Life	Exerc	cise Price Per Share					
\$0.87 - \$1.17	1,130	2.9	\$	1.02					
\$1.36 - \$1.65	579	4.2	\$	1.57					
Total	1,709		\$	1.37					

There were no options exercised during Fiscal 2015 or 2014. The total intrinsic value of options exercised during Fiscal 2013 was \$12,000. The aggregate intrinsic value of (i) options outstanding, (ii) options outstanding and expected to vest in the future and (iii) options outstanding and exercisable at December 31, 2015 was \$563,000, zero and \$563,000, respectively.

NOTE 6 - STOCKHOLDERS' EQUITY AND STOCK COMPENSATION - (continued)

Stock Option Exercises

There were no stock options exercised in Fiscal 2015 or 2014. For Fiscal 2013, we derived net proceeds of \$27,000, as a consequence of the exercise of options to acquire 25,000 of our Common Stock pursuant to the terms of our 2010 Option Plan.

Stock Grants and Other Issuances

In December 2014, we issued 300,000 shares of our Common Stock valued at \$1.31 per share for an aggregate of \$393,000, as payment for a portion of the litigation costs incurred prior to December 31, 2014 related to the Settlement Agreement (defined below). The 300,000 shares of our Common Stock were issued pursuant to an exemption from registration under the Securities Act, by virtue of Section 4(2) of the Securities Act and by virtue of Rule 506 of Regulation D under the Securities Act.

In December 2014, the Compensation Committee of the Board of Directors granted Mr. Karkus 100,000 shares of Common Stock, respectively, under the 2010 Plan valued at \$139,000 as payment for a portion of his Fiscal 2014 bonus.

The 2010 Directors Equity Compensation Plan

On May 5, 2010, our shareholders approved the 2010 Directors' Equity Compensation Plan which was subsequently amended and approved by shareholders on May 6, 2013 (the "2010 Directors' Plan). A primary purpose of the 2010 Directors' Plan is to provide us with the ability to pay all or a portion of the fees of Directors in restricted stock instead of cash. The 2010 Directors' Plan provides that the total number of shares of Common Stock that may be issued under the 2010 Directors' Plan is equal to 425,000 shares. In Fiscal 2015, 2014 and 2013 we granted zero, 28,327 and 16,470 shares, respectively, of our Common Stock valued at zero, \$41,000 and \$27,000, respectively, for director compensation. At December 31, 2015, there are 147,808 shares of Common Stock that may be issued pursuant to the terms of the 2010 Directors' Equity Compensation Plan.

Treasury Stock Acquired Pursuant to a Settlement Agreement

Effective September 4, 2014, we consummated a definitive, global Settlement Agreement ("Settlement Agreement") resolving all of our litigation with certain of the Company's former managers and with certain shareholders. The cases that have been settled include *ProPhase Labs, Inc. v. Quigley, et al.*, Court of Common Pleas of Bucks County, Pennsylvania, Civ. A. No. 2010-08227; *ProPhase Labs, Inc. v. Quigley, et al.*, Court of Common Pleas of Bucks County, Pennsylvania, Civ. A. No. 2011-09815; the appeal filed by the plaintiff in the matter *Quigley v. ProPhase Labs. Inc.'s Officers and Directors, el al*, Court of Common Pleas of Philadelphia County, December Term, 2011, No. 111200409; together with certain ancillary litigation.

The Settlement Agreement amicably resolved these matters and provided, in part, that the parties adverse to the Company in the two Bucks County cases (i) returned to the Company 3,896,764 shares of the Company's Common Stock for which they are listed as the record owners to the Company; and (ii) paid \$440,000 to the Company. In addition, the Company paid \$500,000 to the benefit of one of the defendants and \$37,000 to a third party, to defray certain costs and expenses associated with the Settlement Agreement. Exclusive of legal related costs, the payments received and the payments made pursuant to the Settlement Agreement resulted in a net charge to administrative expense of \$97,000 for Fiscal 2014. Pursuant to the Settlement Agreement, the parties also have agreed to (i) a mutual release of all claims, (ii) a standstill agreement whereby, for a period of ten years, the adverse parties will not acquire Company shares, and (iii) the dismissal of all pending litigation involving the Company, its directors and affiliates on the one hand, and the other parties.

The 3,896,764 shares of Common Stock received pursuant to the terms of the Settlement Agreement were recorded as treasury stock and as an additional contribution to our additional paid-in capital, valued at \$5.1 million, or \$1.31 per share, representing the fair value of the shares at September 4, 2014.

NOTE 7 – DEFINED CONTRIBUTION PLANS

We maintain the ProPhase Labs, Inc 401(k) Savings and Retirement Plan, a defined contribution plan for our employees. Our contributions to the plan are based on the amount of the employee plan contributions and compensation. Our contributions to the plan in Fiscal 2015, 2014 and 2013 were \$134,000, \$101,000 and \$100,000, respectively.

NOTE 8 – INCOME TAXES

The components of the provision (benefit) for income taxes, in the consolidated statements of operations are as follows (in thousands):

		Year Ended December 31,					
	2015			2014		2013	
Current					'		
Federal	\$	-	\$	-	\$	-	
State		<u>-</u>		<u>-</u>	<u> </u>	<u>-</u>	
		-		-		-	
Deferred							
Federal		(1,403)		(2,471)		1,216	
State		(73)		(74)	<u> </u>	(999)	
		(1,476)		(2,545)		217	
Total	\$	(1,476)	\$	(2,545)	\$	217	
Income taxes from continuing operations before							
valuation allowance	\$	(1,476)	\$	(2,545)	\$	217	
Change in valuation allowance		1,476		2,545		(217)	
Income tax (benefit)		_		_		-	
Total	\$	-	\$	-	\$	-	

A reconciliation of the statutory federal income tax expense (benefit) to the effective tax is as follows (in thousands):

	Year Ended December 31,					
		2015		2014		2013
Statutory rate - federal	\$	(1,224)	\$	(2,662)	\$	138
State taxes, net of federal benefit		(305)		(51)		17
Permanent differences and other		53		168		62
Income tax from continuing operation before valuation allowance		(1,476)		(2,545)		217
Change in valuation allowance		1,476		2,545		(217)
Income tax (benefit)		-		-		-
Total	\$	-	\$	-	\$	-

The components of permanent and other differences are as follows (in thousands):

	Year Ended December 31,						
	-	2015		2014		2013	
Permanent items:							
Meals and Entertainment	\$	7	\$	7	\$	7	
Return to provision adjustment		-		-		-	
Charitable contributions		-		1		1	
Share-based compensation expense for stock options							
granted		46		160		54	
	\$	53	\$	168	\$	62	

NOTE 8 – INCOME TAXES - (continued)

The tax effects of the primary "temporary differences" between values recorded for assets and liabilities for financial reporting purposes and values utilized for measurement in accordance with tax laws giving rise to our deferred tax assets are as follows (in thousands):

	Year Ended December 31,						
		2015		2014		2013	
Net operating loss and capital loss carryforward	\$	16,921	\$	14,983	\$	13,569	
Consulting-royalty costs		(8)		39		80	
Trademark		671		752		819	
Investment in Phusion		1,103		(483)		(387)	
Depreciation		(103)		(45)		(34)	
Other		802		2,508		1,009	
Valuation allowance		(19,386)		(17,754)		(15,056)	
Total	\$		\$		\$		

A valuation allowance for all of our net deferred tax assets has been provided as we are unable to determine, at this time, that the generation of future taxable income against which the net operating loss ("NOL") carryforwards could be used can be predicted to be more likely than not. The net change in the valuation allowance for Fiscal 2015, 2014 and 2013 was \$1.6 million, \$2.7 million and \$266,000, respectively. Certain exercises of options and warrants, and restricted stock issued for services that became unrestricted resulted in reductions to taxes currently payable and a corresponding increase to additional-paid-in-capital for prior years. In addition, certain tax benefits for option and warrant exercises totaling \$6.6 million are deferred and will be credited to additional-paid-in-capital when the NOL's attributable to these exercises are utilized. As a result, these NOL's will not be available to offset income tax expense. The net operating loss carry-forwards currently approximate \$44.5 million for federal purposes will expire beginning in Fiscal 2020 through 2034. Additionally, there are net operating loss carry-forwards of \$21.9 million for state purposes that will expire beginning in Fiscal 2020 through 2034.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

PROPHASE LABS, INC. PROPHASE LABS, INC. FOR THE BENEFIT OF PHUSION LABORATORIES, LLC vs. Phosphagenics, Inc., Phosphagenics, LTD and Phusion Laboratories, LLC as a nominal defendant

On October 17, 2014, we initiated a demand for arbitration with the American Arbitration Association, case number 01-14-0001-7373. This demand for arbitration pertains to our Phusion joint venture and the matter is against Phosphagenics, Inc. and Phosphagenics LTD (collectively known as the "Phosphagenics Entities"). We have raised certain claims based upon the Phosphagenics Entities' alleged breach of a certain amended and restated license agreement for the exploitation of certain intellectual property and, separately, breach of the Phusion joint venture operating agreement as between the Company and the Phosphagenics Entities. The Phosphagenics Entities have made counter claims of breaches against the Company and Phusion. The arbitration hearing was held during December 2015 and January 2016 and the evidentiary hearing is now concluded. Each of the parties submitted to the arbitrator their post-hearing briefs on or before March 15, 2016. At this time, no prediction as to the outcome of this action can be made, and we anticipate an arbitral ruling will likely be rendered in or about June 2016.

Other Litigation

In the normal course of our business, we are named as defendant in legal proceedings. It is our policy to vigorously defend litigation and/or enter into settlements of claims where management deems appropriate.

NOTE 9 - COMMITMENTS AND CONTINGENCIES - (continued)

Employment Agreements

On January 14, 2015, we entered into new employment agreements, effective as of January 1, 2015, with Mr. Karkus and Mr. Cuddihy. These January 2015 employment agreements supersede the 2012 Employment Agreements that had been scheduled to terminate on July 15, 2015. On May 29, 2015 we entered into amended and restated employment agreements with each of Mr. Karkus and Mr. Cuddihy (the "2015 Employment Agreements"). The Employment Agreements supersede the employment agreements of Messrs. Karkus and Cuddihy, dated January 1, 2015. The 2015 Employment Agreements were approved by our Compensation Committee.

Under his new amended and restated employment agreement, Mr. Karkus agreed to an annual base salary of \$675,000 as Chief Executive Officer. Mr. Karkus is eligible to receive an annual increase in base salary and may be awarded a bonus in the sole discretion of the Compensation Committee and also will receive regular benefits routinely provided to other senior executives of the Company. In the event of the termination by the Company of the employment of Mr. Karkus without cause or due to a voluntary resignation by Mr. Karkus with Good Reason (as defined in his employment agreement), Mr. Karkus will be paid 1.5 times his base salary ("Mr. Karkus Severance"), with one-half of such amount as a lump sum severance payment in cash and the remaining one-half paid in 12 equal consecutive, monthly installments commencing on the first business day of the month following the effective date of the termination; and all of the stock options and/or restricted stock held by Mr. Karkus shall automatically vest concurrently upon such termination of employment, regardless of any prior existing vesting schedules. If Mr. Karkus is terminated without cause or leaves with Good Reason in contemplation of (or within 24 months following) a change in control of the Company, then, in lieu of the Mr. Karkus Severance payment described above, Mr. Karkus shall instead receive a one-time severance payment in cash equal to the greater of (i) \$1.5 million, and (ii) 199 percent of his average annual total Form W-2 compensation for the three calendar years immediately preceding the date of termination.

Under his new amended and restated employment agreement, Mr. Cuddihy agreed to an annual base salary of \$350,000 as Chief Financial Officer and Chief Operating Officer. Mr. Cuddihy is eligible to receive an annual increase in base salary and may be awarded a bonus in the sole discretion of the Compensation Committee and also will receive regular benefits routinely provided to other senior executives of the Company. In the event of the termination by the Company of the employment of Mr. Cuddihy without cause or due to a voluntary resignation by Mr. Cuddihy with Good Reason (as defined in his Employment Agreement), Mr. Cuddihy will be paid 1.5 times his base salary ("Mr. Cuddihy Severance"), with one-half of such amount as a lump sum severance payment in cash and the remaining one-half paid in 12 equal consecutive, monthly installments commencing on the first business day of the month following the effective date of the termination; and all of the stock options and/or restricted stock held by Mr. Cuddihy shall automatically vest concurrently upon such termination of employment, regardless of any prior existing vesting schedules. If Mr. Cuddihy is terminated without cause or leaves with Good Reason in contemplation of (or within 24 months following) a change in control of the Company, then, in lieu of the Mr. Cuddihy Severance payment described above, Mr. Cuddihy shall instead receive a one-time severance payment in cash equal to the greater of (i) \$900,000 and (ii) 199 percent of his average annual total Form W-2 compensation for the three calendar years immediately preceding the date of termination.

Direct Response Contact

On June 30, 2015, we executed a Direct Response Production Agreement ("DRPA") with Pacific Custom Video Productions Inc. ("PCV") to produce a series of direct response television commercials for certain TK SupplementsTM products. The cost of the commercial development was \$300,000 which was paid in Fiscal 2015 and is included as a component of prepaid expenses at December 31, 2015. As TK SupplementsTM products are launched in Fiscal 2016, these costs will be charged to operations as the products are shipped and television commercial air time is purchased and broadcasted. In addition, the Company agreed to pay to PCV a three percent performance incentive in the form of a royalty (aka commission) of net sales collected, as defined in the agreement, of certain TK SupplementsTM products marketed and promoted with PCV. Performance incentive fees have not been incurred in Fiscal 2015 and will not be incurred until the TK SupplementsTM product line is launched which is scheduled to commence in the first half of Fiscal 2016.

NOTE 9 - COMMITMENTS AND CONTINGENCIES - (continued)

Future Obligations

We have approximate future obligations over the next five years as follows (in thousands):

Year	2015 aployment greements	Godfrey Settlement Agreement	 Notes	 Total
2016	\$ 1,025	\$ 100	\$ -	\$ 1,125
2017	1,025	-	1,500	2,525
2018	512	-	-	512
2019	-	-	-	-
2020	-	-	-	-
Total	\$ 2,562	\$ 100	\$ 1,500	\$ 4,162

NOTE 10 - INVESTMENT IN A JOINT VENTURE

On March 22, 2010, we, Phosphagenics Limited ("PSI Parent"), an Australian corporation, Phosphagenics Inc. ("PSI"), a Delaware corporation and subsidiary of PSI Parent, and Phusion, a Delaware limited liability company, entered into a Limited Liability Company Agreement (the "LLC Agreement") of the Phusion joint venture and additional related agreements for the purpose of developing and commercializing, for worldwide distribution and sale, a wide range of non-prescription remedies using PSI Parent's proprietary patented TPMTM technology ("TPM"). TPM facilitates the delivery and depth of penetration of active molecules in pharmaceutical, nutraceutical, and other products. Pursuant to the LLC Agreement, we and PSI each own a 50% membership interest in the Phusion joint venture.

In connection with the LLC Agreement, PSI Parent granted to us, pursuant to the terms of a License Agreement, dated March 22, 2010 (the "Original License Agreement"), (i) an exclusive, royalty-free, world-wide (subject to certain limitations), paid-up license to exploit OTC drugs and certain other products that embody certain of PSI Parent's TPM-related patents and related know-how (collectively, the "PSI Technology") and (ii) a non-exclusive, royalty-free, world-wide (subject to certain limitations), paid-up license to exploit certain compounds that embody the PSI Technology for use in a product combining one or more of such compounds with an OTC drug or in a product that is part of a regimen that includes the application of an OTC drug.

Pursuant to the Original License Agreement, we issued 1,440,000 shares of our Common Stock having an aggregate value of approximately \$2.6 million to PSI Parent (such shares, the "PSI Shares", which PSI no longer owns), and made a one-time payment to PSI Parent of \$1.0 million. We recorded an intangible asset valued at \$3.6 million in March 2010 for the acquisition of the PSI Technology license.

In September 2014, we began implementing a series of new product development and pre-commercialization initiatives principally in the dietary supplement category. While several of our product development initiatives have advanced, including those specific to the dietary supplement category, our Phusion product development initiatives had not progressed to management's satisfaction. At that time, management believed that any products embodying the licensed technology to be developed by Phusion would not be available until Fiscal 2016 or 2017 at the earliest, and may be more limited than previously forecasted and may encompass fewer products or have limited retail distribution.

During the third quarter of Fiscal 2014, our evaluation of the Company's progress in its new product development pipeline and delays in Phusion product development caused management to reassess projections (including income projections) relied upon in December 2013. Accordingly, management performed an impairment analysis for the period ended September 30, 2014 for the licensed technology. As a consequence of our impairment assessment, we determined that a full impairment occurred of the intangible asset, licensed technology. As a consequence, we charged to operations a \$3.6 million impairment charge during the third quarter of Fiscal 2014.

On October 17, 2014, we initiated a demand for arbitration with the American Arbitration Association, case number 01-14-0001-7373. The Phosphagenics Entities have made counter claims of breaches against the Company and Phusion (see Note 9). At December 31, 2015, cash and cash equivalents includes \$366,000 which is available to be used by Phusion to fund future product development initiatives currently under consideration by PSI Parent, PSI and us.

NOTE 11 – EARNINGS PER SHARE

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Diluted EPS also utilizes the treasury stock method which prescribes a theoretical buy back of shares from the theoretical proceeds of all options and warrants outstanding during the period. Since there is a large number of options and Warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

A reconciliation of the applicable numerators and denominators of the income statement periods presented is as follows (in thousands, except per share amounts):

	Year Ended December 31,									
		2015			2014		2013			
	Loss	Shares	EPS	Loss	Shares	EPS	Income	Shares	EPS EPS	
Basic EPS Dilutives:	\$ (3,600)	16,398	\$ (0.22)	\$ (7,834)	16,773	\$ (0.47)	\$ 405	15,839	\$ 0.03	
Options/Warrants				<u> </u>				437		
Diluted EPS	\$ (3,600)	16,398	\$ (0.22)	\$ (7,834)	16,773	\$ (0.47)	\$ 405	16,276	\$ 0.03	

For Fiscal 2015 and 2014, diluted earnings per share is the same as basic earnings per share due to the inclusion of Common Stock, in the form of stock options and warrants ("Common Stock Equivalents"), would have an anti-dilutive effect on the loss per share. For Fiscal 2015 and 2014, there were Common Stock Equivalents in the amount of 337,186 and 598,609, respectively, which were in-the-money, that were excluded in the earnings per share computation due to their dilutive effect. In addition, for Fiscal 2015, 2014 and 2013, there were Common Stock Equivalents in the amount of 420,500, 26,500 and 472,500, respectively, which were out-of-the-money (the exercise price of the stock option was greater than the average market price for the period), that were excluded in the earnings per share computation due to their dilutive effect

NOTE 12 – SIGNIFICANT CUSTOMERS

Our products are distributed through national chain, regional, specialty and local retail stores throughout the United States. Revenues for Fiscal 2015, 2014 and 2013 were \$20.6 million, \$22.1 million and \$25.0 million, respectively. Walgreen Company ("Walgreens") and Wal-Mart Stores Inc ("Wal-Mart") accounted for approximately 15.8% and 11.3% respectively, for Fiscal 2015. Walgreens, Wal-Mart and CVS Health Corporation ("CVS") accounted for approximately 18.9%, 16.9% and 11.3%, respectively, of our Fiscal 2014 revenues. Walgreens, Wal-Mart and CVS accounted for approximately 20.4%, 14.3% and 11.6%, respectively, of our Fiscal 2013 revenues. The loss of sales to any one or more of these large retail customers could have a material adverse effect on our business operations and financial condition.

We are subject to account receivable credit concentrations from time-to-time as a consequence of the timing, payment pattern and ultimate purchase volumes or shipping schedules with our customers. These concentrations may impact our overall exposure to credit risk, either positively or negatively, in that our customers may be similarly affected by changes in economic, regulatory or other conditions that may impact the timing and collectability of amounts due to us. Customers comprising the five largest accounts receivable balances represented 60% and 67% of total trade receivable balances at December 31, 2015 and 2014, respectively. Management believes that the provision for possible losses on uncollectible accounts receivable is adequate for our credit loss exposure. The allowance for doubtful accounts was zero for both December 31, 2015 and 2014.

NOTE 13 – QUARTERLY INFORMATION (UNAUDITED)

The following table presents unaudited quarterly financial information for Fiscal 2015 and Fiscal 2014 (in thousands, except per share amounts):

	Quarter Ended							
	March 31,		June 30,		September 30,		December 31,	
Fiscal 2015								
Net sales	\$	5,860	\$	2,191	\$	4,390	\$	8,163
Gross profit	\$	3,662	\$	1,008	\$	2,719	\$	4,788
Net income (loss)	\$	(1,380)	\$	(1,566)	\$	602	\$	(1,256)
Basic and diluted income (loss) per share:								
Net loss	\$	(0.09)	\$	(0.10)	\$	0.04	\$	(0.07)
		, , ,		, , ,				, ,
Fiscal 2014								
Net sales	\$	6,171	\$	1,797	\$	5,130	\$	8,972
Gross profit	\$	3,980	\$	792	\$	3,510	\$	5,896
Net income (loss)	\$	(804)	\$	(3,138)	\$	(3,216)	\$	(676)
,		` ,				() ,		
Basic and diluted loss per share								
Net loss	\$	(0.05)	\$	(0.19)	\$	(0.18)	\$	(0.05)
		,		,		,		
		- 54 -						

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that material information required to be disclosed by us in the reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that the information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. We performed an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the disclosure controls and procedures as of the end of the period covered by this report. Based on our review, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Report.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting. Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time. Our system contains self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Our management conducted an evaluation of our effectiveness of the system of internal control over financial reporting based on the framework in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based upon our review, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that the Company's internal controls over financial reporting were effective as of December 31, 2015. *Changes in Internal Control Over Financial Reporting*

There have been no changes in our internal control over financial reporting during Fiscal 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated by reference to the Company's Proxy Statement for the 2016 Annual Meeting of Stockholders (the "2016 Proxy Statement") which is to be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2015 and is hereby incorporated by reference.

Item 11. Executive Compensation

The information required under this item is incorporated by reference to the 2016 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item is incorporated by reference to the 2016 Proxy Statement.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required under this item is incorporated by reference to the 2016 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required under this item is incorporated by reference to the 2016 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Exhibits:

- 3.1 Certificate of Incorporation of the Company, (incorporated by reference to Exhibit 3.3 of Form 8-K filed on June 19, 2015).
- 3.2 By-laws of the Company as amended and restated effective June 18, 2015 (incorporated by reference to Exhibit 3.4 of Form 8-K filed on June 19, 2015).
- 4.1 Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of Form 10-KSB/A filed on April 4, 1997).
- 4.2 Form of Warrant (incorporated by reference to Exhibit 10.3 of Form 8-K filed on December 16, 2015).
- 10.1* 1997 Stock Option Plan (incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-8 (File No. 333-61313) filed on August 13, 1998).
- Exclusive Representation and Distribution Agreement dated May 4, 1992 between the Company and Godfrey Science and Design, Inc. et al (incorporated by reference to Exhibit 10.2 of Form 10-KSB/A filed on April 4, 1997).
- Amended and Restated Rights Agreement, dated as of June 18, 2014 between the Company and American Stock Transfer and Trust Company (incorporated by reference to Exhibit 4.1 of Form 8-K filed on June 19, 2014).
- Form of Indemnification Agreement between the Company and each of its Officers and Directors dated August 19, 2009 (incorporated by reference to Exhibit 10.1 of Form 8-K filed on August 19, 2009).
- 10.5 Limited Liability Company Agreement, dated March 22, 2010, between the Company, Phosphagenics Limited, Phosphagenics Inc., and Phusion Laboratories, LLC. (incorporated by reference to Exhibit 10.11 of Form 10-K filed on March 24, 2010).
- 10.6 Contribution Agreement, dated March 22, 2010, between the Company, Phosphagenics Limited, Phosphagenics Inc., and Phusion Laboratories, LLC. (incorporated by reference to Exhibit 10.12 of Form 10-K filed on March 24, 2010).
- License Agreement, dated March 22, 2010, between the Company and Phosphagenics Limited. (incorporated by reference to Exhibit 10.13 of Form 10-K filed on March 24, 2010).

- 10.08 Amended and Restated License Agreement, dated March 22, 2010, between the Company, Phosphagenics Limited, Phosphagenics Inc., and Phusion Laboratories, LLC. (incorporated by reference to Exhibit 10.14 of Form 10-K filed on March 24, 2010).
- 10.09 2010 Equity Compensation Plan (incorporated by reference to Exhibit B of the Company's Annual Proxy Statement on Schedule 14A filed on April 2, 2010).
- 10.10* 2010 Directors' Equity Compensation Plan (incorporated by reference to Exhibit C of the Company's Annual Proxy Statement on Schedule 14A filed on April 2, 2010).
- 10.11* Amendment to 2010 Directors' Equity Compensation Plan (incorporated by reference to Exhibit 10.3 of Form 8-K filed on May 10, 2010).
- 10.12 * Form of Option Agreement pursuant to 2010 Equity Compensation Plan (incorporated by reference to Exhibit 10.4 of Form 8-K filed on May 10, 2010).
- 10.13* Form of Option Agreement pursuant to 2010 Directors' Equity Compensation Plan (incorporated by reference to Exhibit 10.5 of Form 8-K filed on May 10, 2010).
- 10.14* Form of Restricted Stock Award Agreement pursuant to 2010 Directors' Equity Compensation Plan (incorporated by reference to Exhibit 10.6 of Form 8-K filed on May 10, 2010).
- 10.15* 2010 Amended and Restated Equity Compensation Plan (incorporated by reference to Exhibit A of the Company's Annual Proxy Statement on Schedule 14A filed on March 14, 2011).
- 10.16 Redemption Agreement with Phosphagenics Ltd. (incorporated by reference to Exhibit 10.1 of Form 8-K filed on September 23, 2011).
- 10.17 Investment Agreement by and between ProPhase Labs, Inc. and Dutchess Opportunity Fund II, LP, dated as of May 28, 2014 (incorporated by reference to Exhibit 10.1 of Form 8-K filed on May 28, 2014).
- 10.18 Registration Rights Agreement by and between ProPhase Labs, Inc. and Dutchess Opportunity Fund II, LP, dated as of May 28, 2014 (incorporated by reference to Exhibit 10.2 of Form 8-K filed on May 28, 2014).
- 10.19 Settlement Agreement and Mutual Release between ProPhase Labs, Inc. f/k/a The Quigley Corporation and John C. Godfrey, the Estate of Nancy Jane Godfrey, and Godfrey Science and Design, Inc. dated December 20, 2012. (incorporated by reference to Exhibit 10.25 of Form 10-K filed on March 28, 2013).
- 10.20* Amendment to Amended and Restated 2010 Equity Compensation Plan (incorporated by reference to Appendix A of the Company's Annual Proxy Statement on Schedule 14A filed on April 3, 2013).
- 10.21* Amendment to 2010 Directors' Equity Compensation Plan (incorporated by reference to Appendix B of the Company's Annual Proxy Statement on Schedule 14A filed on April 3, 2013).
- 10.22* Global Settlement Agreement between ProPhase Labs, Inc. and certain of the Company's former managers and with certain shareholders dated September 4, 2014 resolving all litigation matters between the parties (incorporated by reference to Exhibit 99.3 of Form 8-K dated September 4, 2014)
- 10.23* Employment Agreement dated May 29, 2015 between Ted Karkus and the Company (incorporated by reference to Exhibit 99.2 of Form 8-K filed on June 1, 2015).
- 10.24* Employment Agreement dated May 29, 2015 between Robert V. Cuddihy, Jr. and the Company (incorporated by reference to Exhibit 99.1 of Form 8-K filed on June 1, 2015).

- 10.25 Registration Rights Agreement by and between ProPhase Labs, Inc. and Dutchess Opportunity Fund II, LP, dated as of July 30, 2015 (incorporated by reference to Exhibit 4.2 of the registration statement on Form S-8 filed on August 5, 2015).
- Investment Agreement by and between ProPhase Labs, Inc. and Dutchess Opportunity Fund II, LP, dated as of July 30, 2015 (incorporated by reference to Exhibit 4.1 of the registration statement on Form S-8 filed on August 5, 2015).
- 10.27 Subscription Agreements by and between ProPhase Labs, Inc. and John Ligums and Justin Leonard dated December 11, 2015 (incorporated by reference to Exhibit 10.1 of Form 8-K filed on December 16, 2015).
- 10.28 Form of 12% Secured Promissory Note dated December 11, 2015 (incorporated by reference to Exhibit 10.2 of Form 8-K filed on December 16, 2015).
- 10.29 Form of Security Agreement by and between ProPhase Labs, Inc. and John Ligums dated December 11, 2015 (incorporated by reference to Exhibit 10.4 of Form 8-K filed on December 16, 2015).
- 14.1 Code of Ethics (incorporated by reference to Exhibit II of the Proxy Statement on Schedule 14A filed on March 31, 2003).
- 21.1** Subsidiaries of ProPhase Labs, Inc.
- 23.1** Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.

- 31.1** Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2** Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1** Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2** Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - * Indicates a management contract or compensatory plan or arrangement
 - ** Filed herewith
- 40 ** 101 INS XBRL Instance Document
- 41 ** 101 SCH XBRL Taxonomy Extension Schema Document
- 42 ** 101 CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 43 ** 101 DEF XBRL Taxonomy Extension Definition Linkbase Document
- 44 ** 101 LAB XBRL Taxonomy Extension Label Linkbase Document
- 45 ** 101 PRE XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PROPHASE LABS, INC. Registrant

Date: March 29, 2016	By: /s/ Ted Karkus Ted Karkus, Chairman of the Board, Chief Executive Officer and Director
Pursuant to the requirements of the Securities Exchange Act of 1934 registrant and in the capacities and on the dates indicated:	, this report has been signed by the following persons on behalf of the
Principal Executive Officer	Principal Financial and Accounting Officer
By: /s/ Ted Karkus Ted Karkus Chairman of the Board and Chief Executive Officer Date: March 29, 2016	By: /s/ Robert V. Cuddihy, Jr. Robert V. Cuddihy, Jr. Chief Operating Officer and Chief Financial Officer
<u>Dir</u>	<u>ectors</u>
/s/ Jason Barr Jason Barr /s/ Mark Burnett	/s/ Louis Gleckel
Mark Burnett	Louis Gleckel
/s/ Mark Leventhal	/s/ James McCubbin
Mark Leventhal	James McCubbin
Date: March 29, 2016	_
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SUBSIDIARIES OF PROPHASE LABS, INC.

State or other Jurisdiction of Incorporation	Ownership Percentage
Delaware	100%
Delaware	50%
Delaware	100%
Delaware	100%
Delaware	100%
	Delaware Delaware Delaware Delaware Delaware Delaware

The above subsidiaries are included in the consolidated financial statements for the year ended December 31, 2015.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of ProPhase Labs, Inc. and Subsidiaries on Forms S8 (No. 333-73456, No. 333-61313, No. 333-10059, No. 333-14687, No. 333-26589, No. 333-132770 and No. 333-169697), Form SB-2 (No. 333-31241) and Forms S-3 (No. 333-86976, No. 333-104148, No. 333-119748, No. 333-185167, No. 333-196352, No. 333-206090) of our report dated March 29, 2016, on our audits of the consolidated financial statements of ProPhase Labs, Inc. and Subsidiaries as of December 31, 2015 and 2014 and for each of the years in the three-year period ended December 31, 2015, which report is included in this Annual Report on Form 10-K to be filed on or about March 29, 2016.

/s/	EISN	ERA	MP	ER	LL	P

Iselin, New Jersey March 29, 2016

OFFICER'S CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Ted Karkus, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of ProPhase Labs, Inc.;
- 2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 131-15(f) and 15d015(f) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2016

By: /s/ Ted Karkus

Ted Karkus Chairman of the Board and Chief Executive Officer (Principal Executive Officer)

OFFICER'S CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Robert V. Cuddihy, Jr., certify that:

- 1. I have reviewed this Annual Report on Form 10-K of ProPhase Labs, Inc.;
- 2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 131-15(f) and 15d015(f) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2016

By: /s/ Robert V. Cuddihy, Jr.

Robert V. Cuddihy, Jr. Chief Operating Officer and Chief Financial Officer (Principal Accounting and Financial Officer)

PROPHASE LABS, INC. CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934 AND 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Ted Karkus, Chief Executive Officer of ProPhase Labs, Inc., a Delaware corporation (the "Registrant"), in connection with the Registrant's Annual Report on Form 10-K for the period ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), do hereby represent, warrant and certify, in compliance with Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Ted Karkus

Ted Karkus Chairman of the Board and Chief Executive Officer (Principal Executive Officer)

March 29, 2016

PROPHASE LABS, INC. CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934 AND 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert V. Cuddihy, Jr., Chief Financial Officer of ProPhase Labs, Inc., a Delaware corporation (the "Registrant"), in connection with the Registrant's Annual Report on Form 10-K for the period ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), do hereby represent, warrant and certify, in compliance with Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Robert V. Cuddihy, Jr.

Robert V. Cuddihy, Jr. Chief Operating Officer and Chief Financial Officer (Principal Accounting and Financial Officer)

March 29, 2016